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Part II

Environmental Protection Agency

40 CFR Part 266

Storage, Treatment, Transportation, and Disposal of Mixed Wastes; Final Rule

40 CFR Parts 261 and 268

Hazardous Waste Identification Rule (HWIR); Revisions to Mixture and Derived-From Rules; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 266

[FRL–6975–1]

RIN 2050–AE45

Storage, Treatment, Transportation, and Disposal of Mixed Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is today finalizing its proposal to provide increased flexibility to facilities that manage low-level mixed waste (LLMW) and technologically enhanced naturally occurring and/or accelerator-produced radioactive material (NARM) containing hazardous waste. The final rule reduces dual regulation of LLMW, which is subject to the Resource Conservation and Recovery Act (RCRA) and to the Atomic Energy Act (AEA). This final rule conditionally exempts from RCRA hazardous waste management low-level mixed wastes during storage and treatment. The storage and treatment exemption in today's rule requires the use of tanks or containers to store or treat the waste and applies only to low-level mixed waste that meets the specified conditions and is generated under a single Nuclear Regulatory Commission (NRC) or NRC Agreement State license.

Today's rule also exempts LLMW and hazardous NARM waste from RCRA manifest, transportation, and disposal requirements when specified conditions are met. Under this conditional exemption, the waste remains subject to manifest, transport, and disposal requirements under the NRC (or NRC Agreement State) regulations for low-level radioactive waste (LLW) or eligible NARM.

DATES: This final rule is effective November 13, 2001.

ADDRESSES: Supporting materials are available for viewing in the RCRA Information Center (RIC) located at Crystal Gateway One, First Floor, 1235 Jefferson Davis Highway, Arlington, Virginia. The Docket Identification Number is F–2001–ML2F–FFFFF. The RIC is open from 9:00 a.m. to 4:00 p.m., Monday through Friday, except for Federal holidays. To review docket materials you should make an appointment by calling (703) 603–9230. You may copy up to 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page. The index and some supporting materials are available electronically. See the **SUPPLEMENTARY INFORMATION** section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at (800) 424–9346 (toll free), or TDD (800) 553–7672 (hearing impaired). In the Washington, DC metropolitan area call (703) 412–9810 or TDD (703) 412–3323 (hearing impaired). For information on this rule, contact Nancy Hunt at (703) 308–8762 or Chris Rhyne at (703) 308–8658. They are in the Office of Solid Waste (5303W), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION: Use this address to access the rule electronically on the Internet: http://www.epa.gov/epaoswer/hazwaste/radio/:

The official record for this rule will be kept in paper form. Accordingly, EPA transferred all comments received electronically into paper form and placed them in the official record, which also includes all comments submitted directly in writing. The official record is the record maintained at the RCRA Docket Information Center. See the **ADDRESSES** section above.

EPA responses to comments on the March 1, 1999 Advance Notice of Proposed Rulemaking (64 FR 10063) and the November 19, 1999 Storage, Treatment, Transportation, and Disposal of Mixed Waste; Proposed Rule (64 FR 63464) are in a response to comments document placed in the official record for this rulemaking.

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I. References

A. Acronyms Used in This Preamble

AEA—Atomic Energy Act of 1954, as amended
ALARA—As Low As Reasonably Achievable
ANPRM—Advance Notice of Proposed Rulemaking
ARAR—Applicable or Relevant and Appropriate Requirements
BDAT—Best Demonstrated Available Technology
CBI—Confidential Business Information
CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act
DOD—Department of Defense
DOE—Department of Energy
EEI—Edison Electric Institute
EPA—Environmental Protection Agency (referred to as ''we'' throughout this document)
FFCA—Federal Facilities Compliance Act
FUSRAP—Formerly Utilized Sites Remedial Action Program
GWRL—Groundwater Risk Levels
HSWA—Hazardous and Solid Waste Amendments of 1984
HWIR—Hazardous Waste Identification Rule
ICR—Information Collection Request
LDR—Land Disposal Restrictions
LLW—Low-Level Radioactive Waste
LLMW—Low-Level Mixed Waste
LLRWDF—Low-Level Radioactive Waste Disposal Facility
MMR—Military Munitions Rule
NAAG—National Association of Attorneys General
NARM-Technologically Enhanced Naturally Occurring and/or Accelerator-produced Radioactive Material
NGA—National Governors' Association
NNPP—Naval Nuclear Propulsion Program
NRC—Nuclear Regulatory Commission
NTTAA—National Technology Transfer and Advancement Act
OMB—Office of Management and Budget
OSW—Office of Solid Waste
OSWER—Office of Solid Waste and Emergency Response
RCRA—Resource Conservation and Recovery Act
RFA—Regulatory Fairness Act
RIC—RCRA Information Center
RQ—Reportable Quantity
SARA—Superfund Amendments and Reauthorization Act
SBREFA—Small Business Regulatory Enforcement Fairness Act
SQG—Small Quantity Generator
TC—Toxicity Characteristic
TRI—Toxics Release Inventory
TSDF—Treatment, Storage and Disposal Facility
UHC—Underlying Hazardous Constituent
UMRA—Unfunded Mandates Reform Act of 1995
UMTRCA—Uranium Mill Tailings Radiation Control Act
USWAG—Utility Solid Waste Activities Group
UTS—Universal Treatment Standards

B. Definition of Terms Used in the Preamble

Agreement State means a state that has entered into an agreement with the NRC under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919), to assume responsibility for regulating within its borders byproduct, source, or special nuclear material in quantities not sufficient to form a critical mass.

ANPRM (Advance Notice of Proposed Rulemaking) refers in this document to the advance notice published in the **Federal Register** on March 1, 1999 (64 FR 10063) on mixed waste storage.

Certified Delivery means certified mail with return receipt requested, or equivalent courier service or other means that provides the sender with a receipt confirming delivery.

Director refers to the definition in 40 CFR 270.2.

''Eligible Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM)'' is NARM that is eligible for the Transportation and Disposal Conditional Exemption. It is a NARM waste that contains RCRA hazardous waste, meets the waste acceptance criteria of, and is allowed by State NARM regulations to be disposed of at a LLRWDF licensed in accordance with 10 CFR part 61 or NRC Agreement State equivalent regulations.

Exempted waste means a waste that meets the eligibility criteria in § 266.225 and meets all of the conditions in § 266.230, or meets the eligibility criteria in § 266.310 and complies with all of the conditions in § 266.315. Such waste is conditionally exempted from the regulatory definition of hazardous waste described in 40 CFR 261.3.

Generator refers to the definition in 40 CFR 260.10.

Hazardous waste means any material which is defined to be hazardous waste in accordance with 40 CFR 261.3, ''Definition of Hazardous Waste.''

Legacy waste means waste that was generated by past activities and has been in storage beyond RCRA accumulation time periods in 40 CFR 262.34 because appropriate treatment technologies have not been developed, or treatment and disposal capacity has not been available.

License means a license issued by the Nuclear Regulatory Commission, or NRC Agreement State, to users that manage radionuclides regulated by NRC, or NRC Agreement States, under authority of the Atomic Energy Act of 1954, as amended.

Low-Level Mixed Waste (LLMW) means a waste that contains both low-level radioactive waste and RCRA hazardous waste.

Low-Level Radioactive Waste (LLW) is a radioactive waste which contains source, special nuclear, or byproduct material, and which is not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in section11e.(2) of the Atomic Energy Act. (See also NRC definition of ''waste'' at 10 CFR 61.2)

Mixed Waste defined in RCRA as amended by the Federal Facility Compliance Act of 1992, means a waste that contains both RCRA hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act of 1954, as amended.

Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM) means radioactive materials that (1) Are naturally occurring and are not source, special nuclear, or byproduct materials (as defined by the AEA) or (2) are produced by an accelerator. NARM is regulated by the States under State law, or by DOE (as authorized by the AEA) under DOE orders.

NRC or NRC Agreement State license means a license issued by the Nuclear Regulatory Commission or an NRC Agreement State under authority granted by the AEA.

NUREG refers to Nuclear Regulatory Commission publications and documents that include formal staff reports, which cover a variety of regulatory, technical and administrative subjects; brochures, which include manuals, procedural guidance, directories and newsletters; conference proceedings and papers presented at a conference or workshop; and books, which serve a technical purpose or an industry-wide needs. Many of the NUREG documents are listed on the NRC Home Page (*http://www.nrc.gov*).

On-site is defined in the RCRA regulations at 40 CFR 260.10, *et seq.*

Tie-down conditions include NRC guidance documents and policies concerning storage and treatment of LLW which become part of the NRC or NRC Agreement State radioactive materials license by reference.

We or *us* within this preamble means the EPA.

You means a generator, treater, or other handler of low-level mixed waste or Eligible NARM.

C. Who Is Potentially Affected by This Rule?

The conditional exemption for low-level mixed waste (LLMW) storage and treatment applies to any mixed waste generator that has an NRC or NRC Agreement State license to possess radioactive material or to operate a nuclear reactor, so long as the waste is eligible and the generator can satisfy the conditions set forth in today's rule.

The transportation and disposal exemption applies to generators of LLMW and Eligible NARM so long as they meet all specified conditions. Facilities potentially affected by this action include those identified in Table 1.

TABLE 1.—FACILITIES POTENTIALLY AFFECTED

Category	Examples of facilities
Nuclear Utilities	Firms that generate electricity using nuclear fuel as the source of energy and that are licensed by the NRC.
Universities/Academic Institutions	Academic institutions at all levels that are licensed by NRC, or an NRC Agreement State, to use radionuclides for academic, biomedical, and research purposes.
Medical Facilities	Hospitals, medical laboratories, doctors' offices, or clinics that are licensed by NRC or an NRC Agreement State to use radionuclides for health care purposes.
Industrial Establishments	Private companies and institutions, including pharmaceutical companies, and research and development institutions that are licensed by NRC or an NRC Agreement State to use radionuclides.
Government Facilities	Facilities, installations and laboratories operated by State Agencies, and by some Federal Agencies, including, but not limited to, the National Institutes of Health, the National Institute of Standards and Technology, the Veterans Administration and the Department of Defense (except the Naval Nuclear Propulsion Program).
Disposal facilities	Low-level radioactive waste disposal facilities licensed under 10 CFR part 61or by an NRC Agreement State.

The preceding table is not intended to be exhaustive, but rather to provide examples of facilities likely to be affected by this rule. To determine whether you are affected by this regulatory action, you should carefully examine the applicability criteria in this preamble. If you have any questions regarding the applicability of this section to a particular entity, consult the persons listed under **FOR FURTHER INFORMATION CONTACT.**

D. What Is the Legal Authority for Today's Final Rule?

The statutory basis for this rule is in sections 1006, 2002(a), 3001–3009 and 3013 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), the Hazardous and Solid Waste Amendments of 1984 (HSWA), and the Federal Facility Compliance Act of 1992 (FFCA), 42 U.S.C. 6905, 6912(a), 6921–6929 and 6934.

II. Summary of Today's Action

In today's rule we are promulgating a conditional exemption for the storage, treatment, transportation, and disposal of low-level mixed waste (LLMW), and Eligible NARM where specified. As a

waste generator and handler who meets certain conditions specified in 40 CFR 266.230 or 266.315, (a) your LLMW could be exempt from most RCRA Subtitle C storage and treatment regulations, and (b) your LLMW and Eligible NARM could be exempt from most RCRA Subtitle C manifesting, transportation, and disposal regulations. Thus, LLMW, and Eligible NARM where specified, may be conditionally exempted from most RCRA Subtitle C requirements through much of the waste management process.

To claim a conditional exemption you must notify the regulatory agencies specified that you meet the conditions. However, if information you provide on your notification is incomplete or inaccurate, your claim for a conditional exemption is nullified subjecting your waste to RCRA Subtitle C regulation.

A. How Does This Rule Affect the Storage and Treatment of LLMW?

Our rule will allow qualified generators of LLMW to claim a conditional exemption from the regulatory RCRA definition of hazardous waste for mixed wastes stored and treated by the generator under a single NRC or NRC Agreement State license. This conditional exemption acknowledges that NRC regulation for low-level waste (LLW) provides protective regulation of storage and treatment of mixed waste in tanks and containers. This regulatory flexibility applies only to generators of low-level mixed waste who are licensed by NRC or an NRC Agreement State. Once your LLMW is removed from storage or treatment for transportation or disposal, it is subject to RCRA Subtitle C regulation unless it qualifies for the transportation and disposal exemption. Under this rule, if you fail to meet any of the conditions in § 266.230, your LLMW is no longer exempted from the regulatory definition of hazardous waste. As a hazardous waste, your LLMW is subject to RCRA Subtitle C regulation.

B. How Does This Rule Affect Transportation and Disposal of LLMW and Eligible NARM?

Today's rule will allow generators of LLMW and Eligible NARM to claim a conditional exemption from the RCRA regulatory definition of hazardous waste for the manifesting, transportation, and disposal of these wastes. (Throughout this document when we refer to the conditional exemption for manifest, transportation and disposal of LLMW, we also mean Eligible NARM.) If your wastes meet the eligibility requirements and if you meet the specified conditions for the transportation and disposal exemption, then you may manage your wastes as you would solely radioactive wastes. This conditional exemption acknowledges the protection provided by NRC and NRC Agreement States requirements for the manifest, transportation and disposal of the radioactive portion of the eligible waste.

III. Why Are We Issuing This Rule?

A. Response to Dual Regulation Concerns and Inadequate Capacity

Mixed waste is regulated under multiple authorities: RCRA (for the hazardous component), as implemented by EPA or Authorized States; and AEA (for the source, special nuclear, or by-product material component), as implemented by the NRC or NRC Agreement States (for commercially-generated mixed wastes), or the Department of Energy (DOE) (for defense-related mixed waste generated by DOE activities). NARM-contaminated hazardous waste is also regulated under multiple authorities: RCRA (for the hazardous component); and State law (for the NARM component), as implemented by a State agency designated by State law. EPA and NRC recognize that joint oversight of mixed waste has been cumbersome, in part because of the different regulatory approaches of the agencies, and has complicated safe management and disposal of mixed waste. With this rule we are responding to the concerns of mixed waste generators regarding the burden and duplication of dual regulation, as well as concerns about reducing the radiation exposures of workers managing mixed wastes. (See discussion related to decay-in-storage in section VI. A. 4. e. i.)

In addition, mixed waste generators have expressed concerns about limited LLMW treatment and disposal options which can put them in violation of RCRA. These concerns originated because RCRA section 3004(j) generally prohibits the storage of hazardous wastes that are also subject to RCRA land disposal restrictions unless the storage is ''solely for the purpose of the accumulation of such quantities of hazardous waste as are necessary to facilitate proper recovery, treatment or disposal.'' Under EPA's regulation codifying RCRA section 3004(j), we presume that the initial year of hazardous waste storage is for the sole purpose of accumulating a quantity necessary to facilitate treatment and disposal. However, if you store LLMW on-site for more than one year, you have the burden of proving that the storage is for the allowed purpose.

Based on our information collection effort in the ANPRM, published March 1, 1999 in the **Federal Register**, and information from mixed waste generators, we found that treatment technology and disposal capacity for certain LLMW are not always available. We also found that, in some cases, commercial mixed waste treatment facilities have not been willing to accept LLMW for treatment unless there are also disposal options. When disposal options do not exist, generators of LLMW store the waste beyond a year. Because of limited LLMW disposal capacity, we believe it is appropriate to provide safe and legal alternatives for the disposal of LLMW.

We assessed NRC regulations for management of LLW and compared them with EPA's regulations for hazardous waste storage, treatment, transportation, and disposal. Our review found that given the NRC's regulatory controls, human health and environmental protection from chemical risks would not be compromised if we deferred to many of the NRC low-level radioactive waste management practices. Given NRC waste management, we do not believe that the addition of RCRA Subtitle C regulation is necessary to protect human health or the environment. Through this rule, we are providing regulatory relief intended to facilitate the disposal of certain LLMW (such as legacy waste requiring long-term storage due to lack of treatment technology and disposal capacity), that has been stored on-site by NRC licensees as mixed waste subject to both RCRA permitting and NRC licensing requirements.

Ninety individuals and organizations commented on the proposal. In general, utilities, nuclear trade organizations, industry, universities, and some States supported the rule; private citizens, waste treatment and disposal facilities, environmental groups, and other States and universities opposed the rule or expressed concerns. We discuss the major comments of both supporting and opposing views by topic below.

In the preamble of the proposal we specifically sought comment on dual regulation. (See 64 FR 63469.) Of the 90 total comments, 77 from organizations or individuals addressed dual regulation, 61 of which expressed support for a conditional exemption of mixed waste. Several stated that the exemption would provide important and necessary regulatory flexibility for LLMW. Others stated that EPA has developed a sound and compelling technical record for both the storage and treatment of LLMW, as well as for off-site transportation and disposal of

LLMW and Eligible NARM in qualified low-level radioactive waste disposal facilities.

Our approach for addressing the issue of dual regulation of LLMW was opposed in whole or part by 16 commenters. Three commenters felt that EPA should establish a Memorandum of Understanding (MOU) with the Nuclear Regulatory Commission to transfer regulatory authority for mixed waste to NRC and Agreement States. However, an MOU would not allow EPA to relinquish jurisdiction over the hazardous portion of mixed waste. In addition, these commenters did not suggest how the NRC management framework might be changed to provide safer treatment and disposal of hazardous wastes. Our regulatory approach provides flexibility for mixed waste storage, treatment, transportation and disposal which addresses dual regulation concerns, and received the support of many generators who have raised the issue of dual regulation to us in the past.

B. Response to HWIR Consent Decree

The Edison Electric Institute (EEI), the Utility Solid Waste Activities Group (USWAG), and the Nuclear Energy Institute (NEI)—trade groups representing commercial nuclear power plants—were parties to settlement discussions regarding the deadline for the final Hazardous Waste Identification Rulemaking, ETC v. Browner, C.A. No. 94–2119 (TFH) (D.D.C.). On April 11, 1997, the court entered a consent decree which required EPA to propose revisions to the mixture and derived-from rules, 40 CFR 261.3(a)(2)(iv) and (c)(2)(i), and to seek comment on eleven items listed in the decree with respect to those revisions. (See EPA Consent Decree, Ref. 1.) One of the eleven items concerns an exemption from RCRA hazardous waste disposal regulations for low-level mixed waste generated by nuclear power plants where such waste is also subject to regulation by the Nuclear Regulatory Commission. (See Side-bar letter, Ref. 2.) The consent decree required that the proposal also request comment on other regulatory relief for these wastes, if EPA finds that any other relief would be appropriate. (See ANPRM for further information.) This decree requires that EPA take final action on the proposal by April 30, 2001.

Today's rule provides regulatory relief to LLMW generators and other regulatory relief as described in this document. In a separate notice, EPA is revising the mixture and derived-from rules. (See Docket #F–2001–WHWF–FFFFF.) The revision includes an exemption from the mixture and derived-from rule for low-level mixed waste that is managed in compliance with the requirements in part 266, subpart N. These two final rules satisfy EPA's obligations under the consent decree.

C. Response to Petition From USWAG and Concerns of Other Mixed Waste Generators

The Utility Solid Waste Activities Group (USWAG), a national organization of power companies, petitioned the U.S. EPA on January 13, 1992 to amend RCRA Subtitle C regulations governing storage of mixed wastes. The USWAG organization cited difficulties in complying with RCRA Subtitle C regulations because of limited treatment technology and disposal capacity for some mixed wastes. (See discussion in ANPRM for additional information.) Today's action is our response to the USWAG petition.

Policy of Lower Enforcement Priority for Mixed Waste

Recognizing the limitations of available technology and capacity, in 1991 EPA issued a policy on a lower priority for enforcement of the storage prohibition contained in 3004(j) of RCRA for certain waste streams. (See 56 FR 42730; August 29, 1991.) Section 3004(j) prohibits storage of a waste restricted from land disposal (including the hazardous component of mixed waste), except for the purposes of the accumulation of such quantities of hazardous waste necessary to facilitate proper recovery, treatment, or disposal. The lack of adequate treatment technology or disposal capacity for some mixed waste streams necessitated mixed waste storage in violation of land disposal restrictions. The policy stated that violators who were faced with the impossibility of complying with the RCRA regulations, had a RCRA storage permit, and were storing their wastes in an environmentally responsible manner would be a low enforcement priority for EPA. Because treatment technology or disposal capacity was still unavailable for some mixed wastes, we extended this policy in 1994, 1996 and again in 1998. The policy expires on October 31, 2001. (See 63 FR 59989, November 6, 1998.)

This rulemaking is intended to provide flexibility to generators of mixed waste where EPA requirements are to a large extent duplicative of performance standards required by the NRC or NRC Agreement States. With the promulgation of this rule, EPA is stating its determination that facilities that comply with certain criteria can safely store mixed waste at NRC licensed facilities. The prohibition for storage in 3004(j) will not apply to waste that both meets the eligibility criteria of, and is stored in accord with the conditions of, this rule. Thus, the federal government is providing with this rule a potential option for mixed waste generators to store mixed wastes legally. We recognize that States are not required to become authorized for this rule. States may choose to be more stringent than the federal RCRA program. However, since many States have followed EPA's lead on the enforcement policy, we anticipate that most states will choose to address the storage problem of concern to mixed waste generators by adopting this rulemaking.

IV. Precedent for Regulatory Flexibility

A. Military Munitions Rule

The flexibility of this rule is modeled on the conditional exemption developed for waste military munitions in the Military Munitions Rule published February 12, 1997 (62 FR 6622–6657). (See 40 CFR part 266, subpart M.) The Military Munitions Rule (MMR) identifies when conventional and chemical military munitions become hazardous wastes subject to RCRA Subtitle C. In the MMR, EPA developed a conditional exemption to provide regulatory flexibility to storers and transporters of non-chemical waste military munitions. EPA provided the exemption for waste military munitions because the Defense Department Explosives Safety Board (DDESB) standards apply to and are binding on the military, and there is an institutional oversight process within the military. (See 62 FR at 6636.) Under the conditional exemption, non-chemical waste military munitions that normally meet the definition of ''hazardous waste'' are exempt from the regulatory definition of hazardous wastes under RCRA Subtitle C so long as the facilities storing or transporting munitions meet all of the conditions listed in the rule. (For the complete text of the Military Munitions Rule preamble, see 62 FR 6621, February 12, 1997.)

The U.S. Court of Appeals for the D.C. Circuit upheld all aspects of the MMR in Military *Toxics Project* v. *EPA,* 146 F.3d 948 (D.C. Cir. 1998). The court agreed with EPA that ''Congress has not spoken directly to the issue of conditional exemption,'' and upheld as reasonable EPA's interpretation that 3001(a), which requires the Administrator to promulgate criteria for identifying and listing wastes that should be subject to Subtitle C requirements, allows the use of

conditional exemptions. (Id.) The court also agreed with EPA that ''where a waste might pose a hazard only under limited management scenarios, and other regulatory programs already address such scenarios, EPA is not required to classify a waste as hazardous waste subject to regulation under Subtitle C.'' (Id. at 958.) For a more complete explanation of the legal basis for establishing a conditional exemption under RCRA, see the preamble to the Military Munitions Rule at 62 FR 6636. Today's final rule recognizes the safeguards which the NRC or NRC Agreement State regulatory program for low-level radioactive wastes already provides during storage, treatment, transportation and disposal. State radiation programs address NARM wastes under separate authorities.

B. Applying the Conditional Exemption Concept to Mixed Waste

In the Military Munitions Rule, EPA conditionally exempted from RCRA Subtitle C regulation stored waste military munitions and waste military munitions transported from one military owned or operated facility to another that are subject to DDESB standards. We take a comparable approach for generators of LLMW in this rule, which provides a conditional exemption for the storage, treatment, transportation, and disposal of LLMW that is subject to NRC or NRC Agreement State regulation. The exemption is based on the NRC or the NRC Agreement State licensing process and regulatory requirements, and their adequacy in addressing risks from both radioactivity and RCRA hazardous constituents. By promulgating a conditional exemption, we can eliminate redundant or dual requirements where wastes are managed safely; the NRC-required safeguards are in place (for example, inspection, recordkeeping, reporting); and penalties or other consequences may be imposed if the governing regulatory framework is not followed. Taking these features together, EPA concludes that these wastes should not be regulated under Subtitle C, because the NRC regulatory framework ensures protection of human health and the environment.

1. Evaluation of NRC Storage and Treatment Requirements

The NRC was created as an independent agency by the Energy Reorganization Act of 1974, which abolished the Atomic Energy Commission (AEC) and moved the AEC's regulatory function to NRC. This act, along with the Atomic Energy Act of 1954, as amended, provides the foundation for regulation of the nation's commercial nuclear power industry. The NRC's scope of responsibility includes regulation of commercial nuclear power reactors; non-power research, test, and training reactors; fuel cycle facilities; medical, academic, and industrial uses of nuclear materials; and the transport, storage, and disposal of nuclear materials and waste.

NRC regulations are issued under the United States Code of Federal Regulations (CFR) Title 10, Chapter 1. Regulation of LLMW is addressed through the issuance of regulations including those found in 10 CFR parts 20, 30, 35, 40, 50, 61, 70, and 71. NRC interprets these regulations and offers guidance on how licensees should comply with them through numerous Criteria, Regulatory Guides, Generic Communications, and NRC Reports.

Licenses that are issued on the basis of NRC's regulatory system allow entities to manage nuclear materials including wastes. Conditions of these licenses are enforced by NRC's Office of Enforcement, which oversees, manages, and directs the development and implementation of policies and programs for enforcement of NRC requirements. The system in place provides a comprehensive framework for the safe management of the various forms of waste generated by the nuclear industry, including LLMW. The NRC shares with EPA a common responsibility to protect the public health and safety.

In considering a conditional exemption from RCRA Subtitle C regulation for storage and treatment of low-level mixed waste generated by an NRC or NRC Agreement State licensee, we evaluated certain key factors. First, we reviewed the licensing requirements and NRC standards for the storage and treatment of LLW to determine whether NRC regulation of stored low-level waste adequately protects against possible risks from RCRA hazardous constituents in mixed waste. Although NRC regulation and oversight are designed primarily to address risks posed by radiation, the NRC, the regulated industry, and others have argued that these standards largely duplicate RCRA requirements and also protect against risks to human health and the environment posed by hazardous waste.

Second, we compared NRC low-level waste and EPA hazardous waste storage and treatment requirements. (See Ref. 4, EPA Comparison of Storage and Treatment Requirements, for details.) We found that activities performed by a licensee to safely store, treat, or address the release of the radioactive component of mixed waste also resulted in the safe management of the hazardous waste of the LLMW matrix. This result is attributable to the nature of mixed wastes—that is, migration of hazardous constituents does not occur except in the presence of radionuclides. Our analysis was conducted independently of similar studies performed by USWAG, the Electric Power Research Institute, and the Nuclear Management and Resources Council, Inc. (who represent members of the power generation industry). (See proposal F–1999–ML2P–FFFFF, Ref. 6 and 16 for the industry studies.) These other studies concluded that the technical design and operating standards of the NRC meet or exceed RCRA standards in virtually all respects, though the other studies note differences in implementation and emphasis (for example, NRC requirements are performance based whereas EPA's requirements under RCRA are prescriptive. NRC licenses are specifically tailored to the site, whereas RCRA permits are based on national standards.)

Third, we reviewed the compliance history of licensed facilities. We investigated a variety of NRC produced violation summaries for the years 1993–1998. These reports included: Office of Enforcement Annual Report-Fiscal Year 1996; Office of Enforcement Annual Report-Fiscal Year 1997; and Escalated Enforcement Actions Issued Since March 1996 for Reactor Licensees (Last Updated August 14, 1998). For Agreement States, Integrated Materials Performance Evaluation Program NRC Reviews were analyzed for 17 States. We looked at these and other records for documentation of incidents involving the storage and on-site treatment of radioactive wastes by LLMW generators who are licensed users of radionuclides. Our review found that, with few exceptions, the sampled NRC licensed facilities had excellent low-level waste management safety records. (See proposal F–1999–ML2P–FFFFF, Ref. 3, EPA's compliance record review.) Based on our evaluation of these factors, we concluded that low-level mixed wastes stored and treated at these facilities are safely managed and not likely to pose a threat to human health and the environment.

Two environmental groups suggested that EPA should undertake research on the potential synergistic effects of radioactive and hazardous constituents in wastes with the goal of making exposure standards for protecting individuals more restrictive. We note that NRC requires licensed facilities to manage LLW (in both the design of the facility and in its standard operating

procedures) to prevent releases, explosions, fume generation, accidental ignition, and reaction of ignitable wastes that could result from improper mixing or from instability of some LLW. In addition, one of the conditions for the storage exemption is that generators must store low-level wastes in tanks or containers in compliance with chemical compatibility requirements, to prevent chemical interactions. (See § 266.230 [b][2].) Management of the waste adhering to these requirements will avoid potential synergistic effects during storage, or avoid impairment to human health or the environment. The disposal exemption requires both treatment to the levels specified in the Land Disposal Restrictions, and placement in specific types of containers prior to disposal at a Low-Level Radioactive Waste Disposal Facility. Moreover, existing NRC requirements prohibit the disposal of liquid wastes in LLRWDFs. The Agency concludes that potential synergistic effects have been addressed because these conditions must be met to qualify for and maintain a conditional exemption, and the conditions are designed to ensure no contact, or minimal contact, between the waste materials and human and environmental receptors. Finally, EPA is not aware of any such synergistic effects being documented for the waste types being exempted, and has no reason to suspect them. The current system of dual regulation does not take any such effects into account. Should EPA determine in the future that such effects exist, it could re-evaluate the protectiveness of the NRC regime. In the meantime, EPA believes the conditional exemption will be as protective as the current system.

2. Review of NRC Disposal Requirements

In considering the transportation and disposal conditional exemption, we also evaluated certain key factors. First, we compared EPA's and DOT's hazardous waste manifest and transportation requirements with NRC's and DOT's low-level radioactive waste manifest and transportation requirements. We found that the waste tracking and transportation requirements for LLW are either equal to or more restrictive than those required by EPA for treated RCRA hazardous waste. DOT concurred with our assessment that the transportation requirements for LLW are equivalent, if not more restrictive than, the transportation requirements for a RCRA hazardous waste that has been treated and has met LDR treatment standards. (See Ref. 19, Discussion with DOT on Mixed Waste Transportation on August 1999.) As a result, requiring compliance with RCRA hazardous waste manifest and transportation requirements would be redundant and, therefore, unnecessary.

Second, we compared EPA's disposal requirements with NRC's LLW disposal practices and requirements. We reviewed NRC requirements and the practices of low-level waste disposal facilities to determine if NRC provides levels of human health and environmental protection similar to RCRA Subtitle C protection for permitted disposal facilities. (See proposal F–1999–ML2P–FFFFF, Ref. 7, Technical assessment of LLRWDFs.) Our review indicates that NRC regulations for disposal facilities provide protection comparable to that provided by RCRA particularly given that we are requiring that the RCRA hazardous constituents be treated to LDR treatment standards, and that the waste be placed in certain types of containers prior to disposal. We believe that LLMW and Eligible NARM treated, placed in containers, and disposed of at these facilities are not likely to pose a threat to human health and the environment. Therefore, RCRA Subtitle C regulation for these wastes is not necessary to ensure protection of human health and the environment.

V. How Are the Final Storage and Treatment Provisions Different From the Proposal?

The final rule contains a number of language changes to respond to comments, including changes to make the wording for storage and treatment exemption more closely parallel to the wording for transportation and disposal exemption. However, the final rule maintains the conditional exemption for storage, treatment, transportation, and disposal. The changes to our proposal for storage and treatment are highlighted below, and are discussed in greater detail in Section VI of this preamble. The changes to our proposal for transportation and disposal are highlighted in Section VII, and are discussed in greater detail in Section VIII of this preamble.

A. Streamlined Language

In the final rule we have streamlined the eligibility criteria and conditions to remove overlapping and, according to some commenters, redundant language. For example, in our proposal we had said that to be eligible for this conditional exemption LLMW must be managed under an NRC or NRC Agreement State license. We also had listed a condition that you must have a valid NRC license. We have dropped this overlapping language. In another example, our proposal included a condition which stated that you must meet the eligibility criteria. However, it is obvious that if you do not meet the eligibility criteria you cannot claim the exemption. The condition was not necessary as the threshold eligibility criteria must be met first. We note that while eligibility criteria are considered threshold matters, your waste must continue to meet the eligibility criteria to remain exempt.

We moved two of the eligibility criteria we specified in our proposal. (See 64 FR 63498, § 266.225.) These criteria were related to waste storage which meets the requirements of your license for storing LLW and storage in compliance with chemical compatibility requirements. These provisions appear in the final rule in § 266.230 as conditions that you must meet and maintain.

B. Eligibility Revisions

In the final rule we have specified that LLMW eligible for the exemption must be generated and managed by you under a single NRC or NRC Agreement State license. This language replaces the proposed language ''stored on-site.'' The change was based upon comments received on this provision. (See in-depth discussion in Section VI of this preamble.)

C. Clarifications Related to Inventory and Treatment

Commenters indicated the language we used in the proposal related to the frequency of inventory and the types of acceptable treatment was not clear. In the final rule we have clarified that an annual, not quarterly, inventory is required. Regarding treatment, we have clarified that types of treatment allowable are those that can be done in a tank or container and are allowed under the terms of the NRC or NRC Agreement State license. These clarifications have been made in § 266.230 and § 266.235.

D. Recordkeeping Requirements

In our proposal, recordkeeping requirements appeared in two places. We have removed the recordkeeping requirement under the inventory condition proposed as § 266.230(f) and consolidated all recordkeeping requirements in § 266.250 of the final rule. Commenters had found the references in our proposal redundant and unclear. We have also clarified that you must keep records relating to meeting the eligibility criteria, and meeting and maintaining the conditions.

These records form the basis of your claim for the exemption.

In addition, compliance with NRC or NRC Agreement State recordkeeping provisions relating to the storage of your waste is no longer a condition in § 266.230. Instead, we are requiring you to keep these records as a RCRA requirement in § 266.250 under the authority of sections 2002 and 3007 of RCRA. This change responds to comments received, and means that you no longer automatically lose the conditional exemption for your waste for failure to maintain records, though you may be subject to enforcement to ensure compliance and may be assessed RCRA fines and penalties if your records are not complete and accurate. If you fail to meet the recordkeeping requirements, you must take prompt action to return to compliance and to correct inaccurate information in your records. You must be able to demonstrate with your records that your waste is eligible and you meet the conditions for the exemption. In addition we included in § 266.240 language from the proposal (at § 266.245) relating to terminating your conditional exemption for serious or repeated noncompliance with any requirement of subpart N. (See further recordkeeping discussion in Section VI.A.4.d.)

E. Implementation

Commenters were confused regarding how RCRA closure applied to existing storage units. We have clarified that interim status and permitted facilities that have storage units which are used only for storage of conditionally exempt low-level mixed waste do not need to go through RCRA closure, but should seek modification of their permits or revise their interim status closure plans after the date this conditional exemption goes into effect. (See detailed discussion in VI.A.4.g.)

VI. Discussion and Response to Major Comments on the Storage and Treatment Conditional Exemption

A. Storage and Treatment—General Discussion of Provisions

We are promulgating today a conditional exemption from RCRA Subtitle C requirements for storage and treatment of low-level mixed waste in qualified tanks or containers. (See 51 FR 10168, March 24, 1986 regarding waste treatment in tanks or containers.) This regulatory flexibility for storage and treatment applies to any generator of LLMW who is licensed by NRC or an NRC Agreement State to manage radioactive materials. Note, the storage and treatment conditional exemption is available only to low-level mixed wastes generated under a single NRC or NRC Agreement State license. The conditional exemption for LLMW applies only while the waste is stored and/or treated in tanks or containers by the generator, and exempts the stored or treated waste from the regulatory definition of hazardous waste found in 40 CFR 261.3. Prior to storage and/or treatment, all relevant regulations related to hazardous waste generators in 40 CFR part 262 apply. In most cases, where exempted wastes are immediately placed in storage, subpart A would apply. When waste is removed from storage or treatment and is transported to any facility with another NRC license (other than to a LLRWDF under the provisions of 40 CFR 266.305), 40 CFR 262.30 through 262.34 and part 262 subpart D will apply.

LLMW must be eligible under § 266.225, and generators must meet the conditions listed in § 266.230. The storage and treatment exemption will be valid only as long as the eligibility criteria and conditions are met.

During storage or allowable treatment of conditionally exempted LLMW, the generator will not be required to have a RCRA permit for the conditionally exempt waste or meet other RCRA Subtitle C requirements. The storage and treatment conditional exemption applies only to LLMW and does not affect other RCRA hazardous wastes a licensee may generate. A RCRA permit may be required for management of those other wastes depending on the circumstances. In such cases, facilities might decide to identify and locate conditionally exempt stored wastes separately from other stored wastes (whether storage by the generator for less than 90 days or permitted storage).

In the regulatory language, we describe which wastes are eligible for the storage and treatment conditional exemption (§ 266.225), what conditions a generator must meet to qualify for the exemption (§ 266.230), and how the exemption will be implemented (§ 266.240 through § 266.260). Under this rule, if you fail to meet the specified conditions, your LLMW is no longer exempted from regulation as a hazardous waste.

1. What Wastes Are Eligible for the Storage and Treatment Conditional Exemption? (§ 266.225)

Low-level mixed waste meeting the definition in § 266.210 is eligible for a storage and treatment conditional exemption if it is generated and managed by you under a single NRC or NRC Agreement State license. Mixed waste generated at a facility with a different license number and shipped to your facility for storage or treatment requires a RCRA permit and is ineligible for this exemption. The types of facilities that may have LLMW eligible for the storage and treatment exemption include nuclear power plants, fuel cycle facilities, pharmaceutical companies, medical and research laboratories, universities and academic institutions, hospitals, and some industrial facilities.

a. Eligibility provisions and changes from storage and treatment proposed regulatory language. The eligibility provision covers two prerequisites that must be met for the waste to be eligible for the storage and treatment conditional exemption:

1. The waste must be a LLMW;

2. The waste must be generated and managed by you under a single NRC or NRC Agreement State license.

We realize there may be instances where one NRC or NRC Agreement State license number might apply to more than one non-contiguous unit. (For example, a generator such as a university may have a storage unit that is not contiguous to the main generating campus, but has the same NRC license number.) In the event that a generator must ship to another non-contiguous storage area under the same NRC license, the rule allows for the shipment of the waste either from the point of generation to the storage location, or from one storage point to another storage or treatment point with the same NRC license number. In the event of a shipment, the hazardous waste manifesting requirements remain in effect, as the eligible waste is still a hazardous waste until such time as it is place in the accumulation storage area. Storage areas will not need a RCRA permit in the case where only LLMW is stored. However, shipment of exempted waste to these storage areas may occur as they will be considered designated facilities for the purpose of this rule, since they continue to be safely regulated under their NRC licenses. (See letter from Elizabeth Cotsworth to J.D. Givens, dated March 27, 1998, Ref. 20.) Storage may, therefore, be either at the generating site or at your accumulation storage unit with the same NRC or NRC Agreement State license number as that under which the waste was generated.

i. Waste is a LLMW (Excludes NARM). We are finalizing a conditional exemption for LLMW because of the dual regulation to which it is subject. NARM does not meet the definition in § 266.210 of low-level mixed waste. We heard from several commenters on NARM. Some assumed we had included NARM as eligible for the storage

exemption; others suggested we do so. To clarify what we intended, eligible NARM in the proposal applied only to the conditional exemption for transportation and disposal. NARM is not included as a waste eligible for the storage and treatment conditional exemption because that exemption is based upon our study of NRC or NRC Agreement State management practices for stored waste. NARM is not regulated by NRC but by individual states or other federal agencies. We did not study State licensing procedures for managing NARM. Therefore, we have not included NARM waste containing hazardous waste in the storage and treatment conditional exemption because it was beyond the scope of our research relating to safe storage and treatment of LLMW.

ii. Waste is generated and managed by you under a single NRC license. In the proposal, we stated that having an NRC license was a condition. However, we now recognize that it was redundant to require an NRC license provision as both a prerequisite for eligibility and a condition. Therefore, we have deleted the license provision as a condition, and retained it as a prerequisite for eligibility. If, at any time, a facility ceases to be subject to an NRC or NRC Agreement State license, then LLMW managed at the facility would become ineligible for the storage and treatment conditional exemption and would become subject to RCRA Subtitle C regulation. Similarly, if the waste has decayed to background levels, and ceases to be subject to LLW regulation, then the waste becomes subject to RCRA Subtitle C. (See VI.A.4.e.) The conditional exemption is predicated on our finding that NRC regulations and oversight provide the controls necessary to ensure that the hazardous portion of an exempted waste will not be mismanaged. It is the NRC license or NRC Agreement State license, issued and enforced by an independent government agency, that assures proper management during exempt storage. A majority of commenters agreed with the appropriateness of requiring an NRC license.

Many commenters specified that the storage and treatment conditional exemption should not apply to DOE wastes because DOE is not subject to oversight by an independent regulatory agency. States expressed similar concerns in comments submitted to us. In addition, based on site treatment plans resulting from the Federal Facility Compliance Act of 1992, DOE and States have reached agreement on compliance orders regarding management of mixed wastes at DOE facilities. We do not intend to affect or disrupt these compliance orders. We continue to believe that DOE's storage and treatment of low-level mixed wastes raises additional and more complex issues. Therefore, as proposed, we are not extending the storage and treatment conditional exemption to DOE.

In this rulemaking, we have relied upon our thorough studies of the safety of generator management of LLW at facilities operating under a single NRC or NRC Agreement State license. These studies indicate that management of the hazardous component of LLMW under an NRC or NRC Agreement State license is unlikely to pose a threat to human health and the environment. We have changed the eligibility criteria from LLMW generated ''on-site'' (as stated in our proposal) to ''under a single NRC or NRC Agreement State license.'' This change from a prescribed RCRA definition of location to an NRC definition is in keeping with the flexibility we have sought in management of stored mixed waste under one regulatory framework. Our study did not focus on licensees who commercially store and treat waste for other generators. We therefore allow LLMW you generate under a single NRC or NRC Agreement State license to be eligible for a storage and treatment conditional exemption.

b. Differences from proposed eligibility for storage and treatment exemption. These final eligibility criteria differ from those proposed in § 266.225 for stored low-level mixed waste. Our proposal said LLMW ''is eligible for a conditional exemption if managed subject to NRC or Agreement State regulations, and if it is: (a) Generated at your facility * * *; (b) stored on-site in a tank or container meeting the requirements of your NRC or Agreement State license for storing low-level waste; and (c) stored in compliance with chemical compatibility requirements. * * *''

We have moved the references in the proposal at § 266.225(b) ''stored in a tank or container'' and (c) ''stored in compliance with chemical compatibility requirements.'' These provisions are combined as a condition in the final rule language at § 266.230(b)(2). The condition must be met initially and maintained in order to keep the exemption. The exemption is automatically lost if the conditions are not met. (See discussion related to loss of the exemption in § 266.240.)

Similarly, the proposed eligibility criteria in § 266.225(b), ''* * * meeting the requirements of your NRC or Agreement State license for storing low-level waste,'' has been moved. In the final rule it is at § 266.230(b)(1) and refers specifically to the requirements of your license that apply to proper storage of low-level radioactive waste. Note that the requirements of your license which relate solely to recordkeeping are identified under the reporting requirements in § 266.250. This separation of safe management of the waste from the records relating to waste management was based on comments received, which argued that the automatic loss of the conditional exemption should be for improper management, and not solely for failure to maintain records.

Another change in the final rule language at § 266.225 relates to the replacement of ''on-site'' with ''under a single NRC or NRC Agreement State license.'' We received numerous comments relating to the question of limiting the conditional exemption to LLMW stored ''on-site.'' We had specifically requested comment related to use of the term ''on-site'' to describe stored wastes meeting our proposed condition and the ''appropriateness of extending a conditional exemption to facilities that own or operate consolidated storage facilities that do not meet our current definition of ''on-site.'' (See 64 FR 63472.) In our preamble, we had also sought comment on a related issue—''whether the conditional exemption should include a storage facility which serves as a consolidation point for a single entity.'' (See 64 FR 63472.)

We received a large number of comments in response to these requests. Most of them recommended that we include, within the scope of the conditional exemption, storage of LLMW at facilities that do not meet the RCRA definition of ''on-site'' in 40 CFR 260.10. Commenters gave several reasons. Several commenters in support of centralized facilities (and commercial TSDFs) believed that consolidation of waste storage would reduce risks to the public because, unlike accumulation areas, centralized facilities are designed for longer term storage. Some of the commenters indicated that applying the RCRA ''on-site'' definition to limit the exemption would result in operational and administrative inefficiencies. These inefficiencies include the need for multiple storage facilities each with its own inventory and inspection schedules and emergency plan. Some commenters indicated that organizations, such as universities and medical institutions, store LLMW at generator owned and operated facilities and under their NRC licenses are able to store LLW for decay. However, the consolidation points these organizations use may not meet the ''on-

site'' definition, nor have a single RCRA permit number. A few of the total commenters noted that consolidation areas were covered by their NRC licenses and were not considered commercial facilities. Several stated that a license under NRC may cover several non-contiguous facilities or generation points that all are owned by one institution.

We agree with these commenters that the consolidation of LLMW in a specially designed and operated consolidation facility will enhance protectiveness and is more efficient than maintaining multiple storage facilities. A number of commenters recommended that we allow LLMW to be transferred from the point of generation (even if off-site) to a centralized waste management facility. We agree as long as the mixed waste is managed under the same NRC or NRC Agreement State license number. This approach will promote the safe handling of LLW in centralized waste management facilities designed for radioactive waste management and decay-in-storage and facilitate compliance with ALARA principles, which seek to reduce exposures and which govern NRC LLW management. (For further discussion see background documents, Ref. 3, ''Review of Waste Management Practices'' and Ref. 4 ''Comparison of EPA's RCRA and NRC's Licensing Requirements.'')

We also received a small number of comments opposing an expansion of the exemption to consolidation areas or storage facilities that do not meet the ''on-site'' definition. (See 40 CFR 260.10.) Some of these commenters maintained that EPA had not explained why management of LLMW should be different from hazardous waste. Others stated that covering off-site generated wastes may cause generators to lose control of their wastes and may create opportunities for abuse. We disagree with these reasons for not expanding our rule to include off-site consolidation points under a single NRC license within the storage conditional exemption. The overall NRC mandate is for protective management of LLW. (See Energy Reorganization Act of 1974, Public Law 93–438, 42 U.S.C. 5801(a).) We explained in our proposal that the NRC management framework is imposed on the waste generator by virtue of their NRC or the NRC Agreement State license. Since it is the controls imposed by this license that provide the basis for the exemption, it makes most sense to have the scope of the exemption be the same as the scope of the license. The ''on-site'' concept in RCRA serves principally to govern the scope of the RCRA permit exemption for hazardous wastes that are accumulated by a generator for a limited time period with limited controls. That concept has no bearing on this rule since the basis for the exemption created today is the protectiveness afforded by another regulatory program.

Further, we do not believe a generator will lose control of the waste. The LLMW must be generated and consolidated in a storage area operated under the same NRC license as the waste was generated. First, as stated above, the waste must be manifested from the generation point to the storage site. In addition, control is maintained by the license and by the conditions that the waste be inventoried annually and inspected quarterly. The NRC or NRC Agreement State framework provides safe management of both the chemical and radiological hazards associated with LLMW. Such management is provided in addition to the license and ''tie-down'' conditions by adherence to NUREG–0933, ''A Prioritization of Generic Safety Issues,'' and by regulations like 10 CFR 61.56, which include many features related to the physical and chemical characteristics of the waste. This management framework provides safeguards against abuse as expressed in the concerns of these commenters. In short, the NRC, or NRC Agreement State, licensing scheme provides substantial controls over waste managed under an NRC license. The commenter here provided no basis to believe that the NRC scheme fails to control the movement of waste, and EPA is not aware of any basis.

c. Treatment and storage facilities managing LLMW from other generators. We are not extending the conditional exemption to those mixed waste facilities that manage wastes from other licensees. We requested comment on whether we should include in the conditional exemption for storage and treatment those mixed waste facilities that manage wastes from other generators. (See 64 FR 63473.) Some of the commenters addressed the issue of whether the scope of the conditional storage exemption should be expanded to include waste treatment and storage facilities that manage wastes from other generators. Many of those who did comment urged EPA to allow commercial storage and treatment facilities that manage LLMW from other generators the opportunity to claim the conditional storage exemption. These commenters cited several reasons to support their position. One reason given was the need of small businesses (for example, one-time or sporadic LLMW generators) who lack sufficient space for storage and decay to have a place to store their waste. A second reason was that the NRC and NRC Agreement State regulatory framework, which safely addresses storage, should also be sufficient for storage or treatment of wastes off-site, provided the off-site facility meets the conditions of the exemption. Commenters arguing the second position said that storage facilities would be able to accept wastes for storage that they currently cannot accept due to regulatory restrictions.

Other commenters, however, maintain that EPA should not expand eligibility for the conditional storage exemption to commercial storage facilities. These commenters believe NRC regulations are not as protective of human health as are RCRA waste management requirements; NRC provides less rigorous oversight of storage facilities as compared with nuclear power plants; NRC lacks enforcement authority over hazardous constituents; and storage facilities would have difficulty keeping track of exempt waste and separating it when necessary. One commenter indicated that commercial storage facilities already have RCRA permits so there would be little burden reduction if they were to operate under a conditional storage exemption. Other commenters stated that allowing storage facilities to operate under the storage exemption would place an additional burden on the host communities. Because commercial storage facilities are in the ''business of managing such materials for compensation,'' some commenters maintained the commercial storage facilities should have RCRA permits and not be eligible for the conditional exemption.

While there may be some small businesses that would benefit as a result of an expansion of the conditional exemption to commercial storage facilities, small businesses that generate only small quantities of waste are eligible under RCRA regulations for conditionally exempt small quantity generator (CESQG) status. (See 40 CFR 261.5.) If it is eligible for CESQG status, a small business may be conditionally exempt from RCRA regulatory requirements based on the very small volume of hazardous wastes or acutely hazardous wastes which they generate. If it is not a small quantity generator, commercial storage facilities (without an exemption) are still available for waste storage (up to one year) and treatment under current regulations.

We also disagree with some of the reasons offered by commenters opposing extending the conditional exemption to waste managed at commercial storage facilities. The focus of this regulatory effort from its

inception has been limited to a response to expressed concerns of generators regarding overlapping regulation of mixed waste still under their control (*i.e.,* at their licensed facility). We did not comprehensively evaluate commercial storage facilities storing wastes for other licensees given the focus of the rule and limitations of time. While we asked for information regarding the relevance of the rule to commercial facilities that manage wastes from other generators, we did not receive data to support opening the exemption to commercial facilities. Although we believe that the quantities of waste shipped to these facilities could be small, some question still remains as to the long-term effect of commercial storage facilities on the management of LLMW. For example, while we do not establish a time limit on the storage of conditionally exempt waste, we continue to believe that it is highly desirable to have a system under which waste is stored for short periods of time before being sent for treatment and disposal. Even without a regulatory time limit, a generator has incentives (such as capacity limitations, management costs and the rising trend in disposal costs) to move waste stored at its facility from storage to treatment and disposal. (See section VI.A.4.e.iii.) A commercial storage facility may have reduced incentives to minimize storage time, since a commercial facility is more likely to have excess capacity to account for fluctuations in waste shipments. In addition, since storage is the main business of such facilities, they are less likely to view waste storage as an ancillary operation to be kept to a minimum. We agree with those who argue that most commercial TSDFs are permitted and should remain so. In addition, by limiting the scope of the exemption to storage and treatment at facilities operating under the same NRC or NRC Agreement State license, the compliance orders which DOE has signed with States pursuant to the FFCA will not be affected. In summary, because we did not thoroughly evaluate commercial facilities, and the other issues associated with these facilities, at this time we are not expanding the storage and treatment conditional exemption to include storage facilities in the business of treating and storing other licensees' wastes.

2. What Conditions Must You Meet To Qualify for and Maintain a Storage and Treatment Exemption? (§ 266.230)

a. Initial condition to qualify—you must notify the Director of your claim. Under § 266.230(a), to qualify for the storage and treatment conditional exemption, you must notify the Director in writing by certified delivery that you are claiming a conditional exemption for a storage unit containing low-level mixed waste. Your notification must be signed by your authorized representative, as defined in 40 CFR 260.10, who certifies that the information in the notification is true, accurate, and complete. You must notify the RCRA regulatory authority of your claim either within 90 days of the effective date of this rule in your State, or within 90 days of when a storage unit is first used to store conditionally exempt LLMW.

You, as the party claiming the conditional exemption, must be able to demonstrate that your waste and storage unit meet the eligibility criteria and all the conditions. Notification is necessary because it provides the Director with a record of your claim for the exemption. Your notification is self-implementing, although we may use our inspection and information collection authorities to verify whether you are meeting the conditions. You will not receive a notice of approval from EPA or the Director.

i. Cross reference to proposed rule. The rule language is reordered, but the wording related to notification is substantively the same as in proposed § 266.230(d). We reordered the language to improve the clarity of the final rule. (See 64 FR 63472.)

ii. Comments we received on storage and treatment notification. We received a number of comments regarding storage and treatment notification. The majority asked that we require generators to notify either the EPA Regional Administrator or the Director. Several commenters mentioned a preference that state hazardous waste programs be notified. Other commenters thought the notification should also be sent to NRC. These commenters also thought that we should require additional information in the notice, such as:

- The scope of activities and type of mixed waste,
- Radiological and chemical characteristics,
- The RCRA waste codes,
- The expected length and method of storage (container or tank type),
- Where waste storage and treatment will take place,
- The type of treatment, and
- A copy of the emergency plan and the NRC license, including the license number and expiration date of the NRC license.

As a result of these comments, we have more clearly spelled out in the notification language in § 266.230(a) basic information which is readily available to a mixed waste generator and which specifically identifies that generator, waste code(s), and storage unit(s). In the final rule, the dated notification must include your name and address, RCRA identification number, NRC or NRC Agreement State license number, the waste code(s) and storage unit(s) for which you are seeking an exemption, and a statement that you meet the conditions of subpart N. We note that some of the information requested by commenters is unnecessary and could change after the initial notification. The purpose of the notification is to identify and notify, not to provide a management plan for the waste. Based on our studies, we can confidently rely on the NRC management framework for conditionally exempted LLMW. The Director will have access to information substantiating your claim in the records you are required to keep. We do not find it is necessary to impose a requirement to provide all of this information in the notification. In particular, providing a copy of the NRC license would be burdensome as it is readily available for a site inspection and is generally quite lengthy. In addition, today's conditional exemption is based on the protectiveness of the NRC regulatory scheme, not on a license-by-license review. In any event, much of this information will be available to a RCRA inspector during a site visit from records that a generator is required to maintain. Of course, after the Director receives your initial notification, information may be requested using information gathering authorities if needed for any reason.

One commenter suggested an annual status report with projected dates for treatment, shipment, and disposal. We do not agree with this suggestion because a status report adds a recurring reporting burden that is not necessary to protect human health and the environment. Since projected dates for treatment, shipment, and disposal may change a status report does not provide useful information regarding safe management. The information is also irrelevant to any of the conditions for the exemption. The fact that a RCRA inspector may follow-up at any time on the claim of exemption to verify that the conditions are met should provide sufficient opportunity to gather needed information. The notification, coupled with the management of this waste under NRC or equivalent NRC Agreement State regulations, provides information on who is managing exempt waste and assurance regarding its safe management. If a generator fails to comply with the eligibility criteria, or

any of the conditions, the generator must notify the Director of the failure under § 266.240(a).

b. Conditions to maintain the storage and treatment exemption (§ 266.230(b)).

i. Store waste in tank or container in compliance with storage requirements of your NRC or NRC Agreement State license.

In the final rule, we state that you must ''store your low-level mixed waste in tanks or containers in compliance with the requirements of your license that apply to the proper storage of low-level radioactive waste (not including those license requirements that relate solely to recordkeeping).'' This condition had been an eligibility provision in the proposed rule at § 266.225(b). In the final rule, the waste management aspects of this condition (relating to storage under your NRC or NRC Agreement State license) have been separated from the recordkeeping aspects related to storage of your LLW. We believe that adherence to NRC licensing requirements is important to the safe storage of the hazardous portion of the LLMW stream. In the proposal, we requested comment on whether this condition should include the loss of the exemption if any LLW storage requirement of the NRC license is not met; or restrict loss of the exemption to those violations which may result in an environmental impact. (See 64 FR 63472.)

Comments Received on Compliance With License Storage Requirements

We received numerous comments on this aspect of the rule. Most of these comments expressed the view that the storage and treatment conditional exemption should be lost only when NRC license noncompliance is specifically related to waste management, and only in situations that may result in adverse environmental impact. Many reasons were given for this view. Commenters expressed concerns for cycling in and out of the exemption because of minor non-compliance such as misspelled names or incorrect phone listings in the emergency plan. Commenters pointed out that NRC can cite a licensee for failure to comply with the licensee's own internal procedures, so a licensee could be in violation of an NRC license condition without any adverse health or environmental impact, or release of hazardous constituents.

Commenters compared failure to meet the requirements of the NRC license with failure to meet RCRA permit requirements. Correction of the failure is required, and the Director may impose a fine or penalty, but the permit is not automatically lost for such a failure. (However, the Director does have the ability to revoke a permit for significant non-compliance. See 40 CFR 270.41 and 270.43.) Commenters indicated that many kinds of errors can be easily corrected, and should not trigger the loss of the exemption nor subject the generator to RCRA Subtitle C regulation. Conversely, other commenters thought a generator should lose the exemption for failing to meet any NRC LLW storage requirement. These commenters said that it would provide a powerful incentive for generators to comply with the conditions.

We believe that the loss of the exemption for failure to meet any NRC LLW storage requirement, including minor requirements not directly related to safe storage, is unwarranted and not necessary to protect human health and the environment. As noted above, the consequence of failure to meet a RCRA permit requirement is not the automatic loss of the permit. Based upon comments supporting a specific condition relating to waste management, and the difficult situations which commenters have brought to our attention, we have revised the condition in § 266.230(b)(1) to read, ''* * * in compliance with the requirements of your license that apply to proper storage of low-level radioactive waste.* * * '' The final rule does not limit the loss of the exemption to events causing adverse environmental impact, but strikes a balance by specifying a loss of the exemption when noncompliance with the condition is related to waste management. We believe it would create considerable uncertainty and great difficulties for purposes of enforcement and compliance assurance, if the RCRA status of the waste turned on the judgment of whether a particular violation might cause an adverse environmental impact.

The recordkeeping requirements related to your NRC license have been moved to section § 266.250. Upon consideration of the comments, we have concluded that reporting compliance is better treated as a requirement rather than a condition. First, given the logic of the conditional exemption, it seems artificial to say that a waste which is not ''hazardous'' under the RCRA regulatory definition becomes ''hazardous'' if a report contains an inaccuracy, even if the waste is still being properly managed. In addition, we agree with the commenters that we should not create a system under which the storage and treatment exemption can be easily lost for minor or inadvertent infractions. Finally, we believe the final rule scheme retains a strong incentive for compliance with recordkeeping requirements. Again, in striking a balance based on comments we received, we provide language in § 266.240(b) that the Director may terminate an exemption, or specify additional conditions, for repeated or serious noncompliance with the requirements of subpart N. (See proposal at § 266.245(b).)

ii. Store waste in compliance with chemical compatibility requirements. You must ''store your low-level mixed waste in tanks or containers in compliance with chemical compatibility requirements of a tank or container in 40 CFR 264.177, or 264.199, or 40 CFR 265.177, or 265.199.'' The rule requires that the waste be compatibly stored in tanks or containers. This condition is found in § 266.230(b)(2) in the final rule. For clarity, this provision has been moved from § 266.225(c) in our proposed rule where it was required for eligibility. The proposed rule language stated LLMW is eligible ''if it is: * * * (c) Stored in compliance with chemical compatibility requirements of a tank or container (See § 264.177, or § 264.199 of this chapter), or (§ 265.177, or § 265.199 of this chapter).'' The language in the final rule is essentially the same as in the proposal. We received a number of comments on eligibility provisions in the proposal. However, none was directed at the proposed eligibility requirement in § 266.225(c) relating to compliance with chemical compatibility requirements. We have therefore retained this provision as a condition and emphasize the importance of meeting this condition to retain the conditional exemption for storage.

iii. Certify that personnel are trained in hazardous waste management. You must certify that facility personnel who manage stored mixed waste are trained in a manner which ensures that the conditionally exempt waste is safely managed and includes training in hazardous waste management and hazardous materials incidents response that meets the personnel training standards found in 40 CFR 265.16(a)(3).'' Personnel managing the waste must be trained in identifying and providing initial response to a release of hazardous constituents as well as in managing radioactive waste. As part of the notification process, you must certify by a written statement that personnel managing stored LLMW are appropriately trained. This condition at § 266.230(b)(3) is the same as our proposal where it appeared at § 266.230(e).

Comments on Storage and Treatment Related to Training

We received a comment that similar training was already required by NRC or an NRC Agreement State license; the commenter felt that the training condition could be deleted. Other commenters believed that proper training was critical, and that the training condition as written in the proposal was reasonable. We determined, based on our studies, that added training in chemical waste management was important to assure protection of human health and the environment. We, therefore, agree with these latter commenters. One commenter objected to the need to certify that personnel had been trained, and recommended we drop the certification. We used the word ''certify'' because we believe that training in hazardous waste management is critical. The certification ensures that the LLMW facility will verify compliance with the training requirements. It provides an assurance to commenters who expressed concerns about the ability of personnel trained in safe management of radioactive materials also to manage hazardous wastes safely, and respond to hazardous materials incidents. The certification also ensures that a record is available for review by an inspector, enabling verification that all personnel involved in managing or handling the exempt stored wastes are aware of the potential hazards of the hazardous portion of these wastes.

iv. Inventory and inspect your waste. You must ''conduct an inventory of your stored low-level mixed waste at least annually and inspect it at least quarterly for compliance with this paragraph (part 266 subpart N).'' An important part of assuring that you comply with the conditions in today's rule is the condition that you perform regular inspections of the areas in which you store exempted waste, as well as an annual inventory of the waste to detect any loss or other mismanagement. We received comments that the proposal was unclear as to what inventory frequency we intended.

Revision to Inventory Language From Proposed Storage and Treatment Exemption

In our November 1999 proposal, at § 266.230(f), we said, ''Inventory your stored low-level mixed waste at least annually; inspect it at least quarterly for compliance with the other conditions of the paragraph; update your inventory records of conditionally exempt LLMW quarterly; and maintain records for three years.* * *'' Several commenters requested that we clarify the inventory frequency; they did not know if we meant an annual or quarterly inventory. We had intended that generators conduct an inventory annually. Therefore, we have deleted the reference to ''update your inventory records of conditionally exempt LLMW quarterly.'' The annual inventory records, copies of the generator's notification of additional claims for conditional exemption of storage units, and records of all shipments for treatment or disposal since the annual inventory will be available to an inspector. These records will enable an inspector to gain access to a complete file of all conditionally exempt LLMW storage units and to verify the amount stored at any given time. Our proposal addressed records requirements in § 266.230(f) and § 266.250. We have consolidated required records maintenance in § 266.250.

v. Maintain an accurate emergency plan (§ 266.230[b][5]). You must ''maintain an accurate emergency plan and provide it to all local authorities who may have to respond to a fire, explosion, or release of hazardous waste or hazardous constituents. Your plan must describe emergency response arrangements with local authorities; describe evacuation plans; list the names, addresses, and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators; and list emergency equipment.'' In our proposal, nearly identical language was found in § 266.230(g). However, in proposed § 266.230(g) we also provided at the end of the paragraph the following reference: ''(See 40 CFR part 265, subpart D.).'' The reference caused confusion. We had intended this reference to serve to identify those aspects of a contingency plan and emergency procedures necessary for managing hazardous wastes during an emergency. Several commenters interpreted that reference as serving as guidance in the development and maintenance of an emergency plan; others interpreted the reference as a requirement. Because we enumerate, within the rule language, the essential components of the RCRA emergency plan, we have dropped the reference. However, the regulations at 40 CFR part 265, subpart D can continue to provide guidance concerning the necessary elements of a comprehensive emergency plan.

c. Modifications to proposed storage and treatment conditions. We have modified the storage and treatment exemption conditions listed at § 266.230 in the proposed rule as described below.

First, we moved the proposed condition to have a valid NRC or Agreement State license (proposed as § 266.230[a]) from the conditions section to the eligibility section (§ 266.225). We made this change because this is best described under eligibility. Before your waste can qualify for the conditional exemption, your waste must be eligible, i.e. managed under an NRC or NRC Agreement State license. If your waste is not eligible, it cannot be conditionally exempt from RCRA Subtitle C regulation. Eligibility criteria are threshold provisions.

Second, we deleted the condition to meet the eligibility criteria (proposed as § 266.230[c]) because we determined that this was basic. A generator could not claim the exemption without first meeting (and maintaining) the eligibility criteria.

Third, we maintained the condition that you notify the regulatory authority in writing by certified delivery that you are claiming a conditional exemption for your low-level mixed waste (proposed as § 266.230(d) and finalized as § 266.230(a)). Your notification must be signed by an authorized representative of your establishment who certifies that the information in the notification is true, accurate, and complete. You must notify your regulatory authority of your claim either within 90 days of the effective date of this rule in your State, or within 90 days of when a storage unit is first used to store conditionally exempt low-level mixed waste. Your dated notification must include identifying information such as your name and address, your RCRA generator ID number, your NRC license number, and the name of your authorized representative signing the notice. In addition, your notification must indicate that you meet all the conditions for the exemption, and indicate the waste and storage unit for which you are claiming the exemption.

Fourth, both to streamline the regulatory language, and to make clear the conditions that you must meet and maintain for your waste to qualify for the conditional exemption, we combined and moved the eligibility criteria proposed in § 266.225(b) and (c) to § 266.230(b). Based on comments we clarified these conditions that must be met and maintained.

We received considerable comment on whether claimants should be required to comply with all the requirements of their NRC or NRC Agreement State license, or with just those provisions that related to the management of conditionally exempt LLW (i.e., those provisions, which if violated, could result in an

environmental impact from the exempted waste). In response, we modified the proposed condition that claimants must be in compliance with the requirements of their license for storing LLMW (proposed as (§ 266.230[b]). This modification resulted in the condition ((§ 266.230[b][1]), which requires you to store your LLMW in tanks or containers in compliance with the requirements of your license that apply to the proper storage of LLW (not including those license requirements that relate solely to recordkeeping).

The remaining conditions—proposed as § 266.230(e), (f), and (g)—are being finalized as § 266.230(b)(3), (4), and (5), respectively. Specifically, claimants still must:

- Certify that facility personnel who manage stored conditionally exempt LLMW have been trained in a manner that ensures that the conditionally exempt waste is safely managed and includes training in chemical waste management and hazardous materials incidents response that meets the personnel training standards found in 40 CFR 265.16(a)(3);
- Conduct an inventory of your stored conditionally exempt LLMW at least annually and inspect it at least quarterly for compliance with part 266 subpart N; and
- Maintain an accurate emergency plan and provide it to all local authorities who may have to respond to a fire, explosion, or release of hazardous waste or hazardous constituents. Your plan must describe emergency response arrangements with local authorities; describe evacuation plans; list the names, addresses, and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators; and list emergency equipment.

3. Treatment (§ 266.235)

a. Treatment Clarification. In the proposed § 266.235, we allowed treatment of LLMW by generators in a tank or container covered by the provisions of their NRC or NRC Agreement State licenses, but we excluded ''thermal treatment, such as incineration.'' The proposal was intended to make the storage and treatment conditional exemption consistent with the types of treatment NRC currently allows in a tank or container. By excluding thermal treatment we inadvertently have excluded some treatment (for example, drying processes) which the NRC has allowed in tanks or containers. It was not our intent to limit treatment currently allowable in tanks and containers. We, therefore, revised the regulatory language in § 266.235. Our clarification reflects the level of flexibility originally intended. As we explain below, however, forms of treatment that are done in units other than tanks and containers are not exempt from RCRA Subtitle C requirements. Treatments such as incineration, molten salt and super critical water oxidation would not be exempt and would require a RCRA permit.

b. Comments received on treatment. We heard from a number of commenters regarding the conditional exemption for treatment of LLMW in tanks and containers. As discussed below, the majority of the commenters approved of the conditional exemption for treating LLMW at a generator's NRC licensed facility in tanks and containers, many noting that this option would provide a valuable opportunity to process waste at their facilities for safer storage and disposal. However, a number of commenters requested that we consider expanding the scope of the exemption to include thermal treatment, while a few commenters requested that we not allow generators to conduct any form of treatment without a RCRA permit.

i. EPA should reconsider allowing treatment. We heard from several commenters who specifically requested that EPA reconsider any exemption of any storage or treatment activities involving LLMW from the RCRA permitting requirements. One commenter believed that when it comes to LLW and LLMW, the NRC appears to be more concerned with radionuclides than the potential chemical hazards. Thus the commenter said EPA should consider which treatment and storage processes, as defined under RCRA, require permitting and which processes may be exempted due to small scale, low risk of personal or environmental hazard, or similar concerns.

Another commenter, citing experience as a fully licensed and permitted mixed waste TSDF, is concerned that the treatment, transportation, and disposal exemptions are premised upon a generator being able to treat its waste properly to meet LDR requirements. The commenter stated that experience has proven treatment to be a highly technical process requiring the proper equipment, the proper treatment formulae, and careful monitoring. The commenter noted that a treatment failure could result in the subsequent closing of the ''disposal facility as a RCRA Subtitle C facility, if the waste cannot be retrieved or if its hazardous constituents cannot be delisted.''

Another commenter stated the treatment exemption is redundant because generators already are allowed to treat and store RCRA wastes (including LLMW) without a RCRA permit within 90 days, and questioned whether we intended to capture the spectrum of legacy wastes. The commenter opposed our extension of the conditional exemption to legacy wastes. The commenter alleged that many wastes have already been stored for numerous years despite existing treatment and disposal capacity because of cost reasons. The commenter stated that the exemption would allow LLMW generators to further delay the treatment and disposal of legacy wastes. The commenter concluded that extended treatment and storage of LLMW is in no way protective of human health or the environment.

We disagree with the commenters' assertions that the storage and treatment conditional exemption is not protective of human health and the environment. We agree that the NRC licensing framework for storage and treatment of LLMW is geared primarily to protection against radiological hazards through treatment and containment of radionuclides. However, one of Congress' purposes in establishing the NRC is to ''advance the goals of restoring, protecting, and enhancing environmental quality, and to assure public health and safety.'' (See Energy Reorganization Act of 1974, Pub. L. 93–438, 42 U.S.C. 5801(a)).

This statutory purpose is reflected in NRC's mission statement. ''The mission of the U.S. Nuclear Regulatory Commission (NRC) is to ensure adequate protection of the public health and safety, the common defense and security, and the environment in the use of nuclear materials in the United States.'' (See *http://www.nrc.gov.*) Therefore, EPA and NRC share a common mandate to protect human health and the environment.

Moreover, we conducted studies and analyses to determine the protectiveness of the NRC's regulatory framework for managing LLW. (See 64 FR 63497; Section VII., Supporting Documents.) We determined that the various management requirements with regard to treatment, primary and secondary containment, inspections, etc., provide protection for the hazardous constituents in the mixed waste that is comparable to the protection provided by RCRA. We found that NRC has extensive experience with waste compatibility and stability. For example, NRC requires facilities to consider the chemical properties (including ignitable, reactive, and

explosive properties) of their LLW both in the design of the LLW facility, and in writing the standard operating procedures for the facility and associated waste handling systems, storage containers, and storage areas to prevent accidental mixing of incompatible wastes. The intent of the NRC licensing and EPA RCRA programs are equivalent in that both programs require the anticipation, recognition, and prevention of accidental ignition, reaction of reactive wastes, releases, explosions, and fume generation resulting from improper mixing procedures or from the inherent instability of some wastes.

Our studies also included a review of the storage and treatment compliance record of a number of licensees. Violation rates at these facilities compared favorably with RCRA facilities and demonstrate that NRC licensed facilities operate under a regulatory scheme that assures that waste is protectively managed. Based on our studies we concluded that NRC storage and treatment regulations and license requirements regarding storage and treatment are at least as stringent and protective of human health and the environment as RCRA's Subtitle C system. (See ''Comparison of the EPA's RCRA Requirements and the NRC's Licensing Requirements for the Treatment [In Tanks & Containers] and Storage of Low-Level Mixed Wastes at Nuclear Facilities,'' Final Document, April 2001, Ref. 4.) Therefore, we will allow NRC licensees to treat LLMW in tanks and containers. We note that today's rule is consistent with existing RCRA regulatory interpretation which allows treatment in tanks and containers by a generator without a permit. (See 51 FR 10168.)

With regard to the commenter who was concerned with generators' being able to treat their wastes to the applicable LDRs and the potential consequences a LLRWDF, we note that the majority of the volume reduction and chemical stabilization and encapsulation processes that these generators currently conduct at their facilities in tanks and containers are no different from the treatment processes used at RCRA permitted commercial TSDFs. While some generators may have to request a license modification to change their current processes (for example, add a stabilization step) to meet the LDRs, this adjustment would be approved under the auspices of the generator's license. In addition, an NRC or NRC Agreement State licensed LLRWDF may require testing data, and/or conduct verification testing itself, to document that wastes meet the applicable LDR treatment standards prior to the acceptance and subsequent disposal of these treatment residues. In any event, there are potentially significant enforcement consequences if the waste does not attain LDRs, providing a strong incentive for the parties involved to meet LDR levels. If a generator is uncertain of its ability to treat its waste to comply with LDRs, the generator has the option of sending the waste to a permitted TSDF for treatment, or of continuing to store the waste until permitted treatment capacity exists.

We disagree with the commenter's characterization of legacy wastes as wastes that could have been treated years ago, but were not because of cost issues. As the commenter noted, many of these wastes have been in storage for several decades; these wastes remained in storage because legacy wastes, by definition, are wastes for which treatment or disposal capacity does not exist. Although the federal government and industry have conducted significant research on innovative waste treatment and management methods, much more needs to be done before acceptable treatment processes and management methods are developed for all legacy wastes. In addition, siting of new low-level radioactive waste disposal facilities continues to be difficult.

Finally, there appears to be some confusion on the part of commenters as to the time period allowed for treatment by a generator under this exemption. Today's rule allows generators to treat their mixed waste in tanks and containers at their facilities in accordance with the terms of their NRC or NRC Agreement State license without a permit and without a time constraint, in view of the protection afforded by the NRC scheme.

ii. EPA should broaden the scope of treatment in the storage and treatment conditional exemption. We heard from a number of commenters who specifically requested that we consider widening the scope of the conditional exemption to approve thermal treatment if allowed under the generator's NRC or NRC Agreement State license. Many of these commenters were concerned that the prohibition proposed in § 266.235 on conducting any form of thermal treatment would inappropriately bar otherwise sound LDR treatment options for mixed waste containing organic constituents. Though these commenters did not raise objections to our ban on incineration, they believed that the practical effect of the thermal treatment prohibition was that treatment of any mixed waste containing organic constituents would have to be conducted off-site at RCRA permitted mixed waste commercial treatment, storage, and disposal facilities, assuming any are available. Some of these commenters noted that there are numerous thermal technologies that are not, or do not rely on incineration or ''open flame combustion,'' including evaporation, steam reforming, high temperature catalytic oxidation, super critical water oxidation, and molten salt technology. Several of these commenters stated that a blanket prohibition against thermal treatment could deter the development of new and innovative treatment processes. They argued that a complete ban on any type of thermal treatment was overly broad and unnecessary, limiting otherwise viable, cost effective, and environmentally sound treatments available to NRC licensees. These commenters further suggested that the exemption should provide for a risk-based variance mechanism from any thermal treatment prohibition because they believe such an approach would provide a strong incentive for innovative waste treatment vendors to develop new and protective treatment methods.

We also heard from several commenters who wanted any treatment option approved in an NRC or NRC Agreement State license to be permissible under the storage exemption. They suggested that we clarify treatment to reflect this. Some of these commenters noted that clarification is necessary because the text proposed in § 266.235 could be misinterpreted to limit treatment types to solidification, neutralization, or stabilization, when in fact, additional forms of treatment (other than thermal treatment) may be allowed under the NRC or NRC Agreement State license. Another commenter recommended that we remove ambiguity by specifying exactly what treatment options the generator can expect to apply. That is, the EPA should specify by code which treatment options are considered allowable treatment technologies, or prohibited treatment technologies. Two of the commenters also recommended that EPA either delete the specific examples referenced in the second sentence of proposed § 266.235 or, alternatively, make clear that they are only examples to eliminate ambiguity. Commenters also suggested that the conditional exemption should be modified to allow for treatment in other than tanks and containers, provided that it is carried out within a controlled area such as a laboratory, is performed under NRC or NRC Agreement State

regulations and approval, and that there are no uncontrolled releases of hazardous substances to the environment. These commenters believe that the NRC safeguards are an adequate alternative to EPA permit requirements for most aspects of treatment facility operations.

We agree that the scope of the conditional exemption should include any type of treatment that generators can conduct in tanks and containers at their facilities in accordance with the terms of their NRC or NRC Agreement State license. As stated, we have revised the regulation language to drop the blanket restriction on thermal treatment since we had not intended in the proposal to limit the forms of treatment that could be conducted in licensed tanks or containers.

We are not, however, extending the storage and treatment conditional exemption to all forms of treatment that might be allowed under a generator's NRC or NRC Agreement State license. We did a thorough comparison of NRC's requirements for storage and treatment in tanks and containers with RCRA Subtitle C's requirements and concluded that our regulations and guidance governing generator storage and treatment in tanks and containers and NRC's are generally equivalent. (See our background document ''Comparison of the EPA's RCRA Requirements and the NRC's Licensing Requirements for the Treatment [In Tanks and Containers] and Storage of Low-Level Mixed Wastes at Nuclear Facilities.'') We did not do a comparative study comparing what NRC would require for treatment that occurs outside of tanks and containers with RCRA subtitle C requirements. For example, we did not evaluate the requirements NRC would impose on a LLW incinerator with the requirements that EPA would impose under 40 CFR part 264 subpart O on a hazardous waste incinerator.

For these reasons, consistent with current regulations for accumulation of waste in tanks and containers, we are limiting the allowable forms of treatment under the conditional exemption for storage of LLMW to only those forms that can occur in tanks and containers. Treatment that could qualify includes, but is not limited to, those treatment types that occur within a tank or container, such as certain forms of thermal treatment, neutralization, solidification, or other forms of stabilization. The rule no longer cites these examples, since they may appear exclusive. We do not want to exclude all technologies that might rely on some degree of heat.

Finally, because this conditional exemption relies upon waste handlers monitoring their compliance with the conditions, we do not believe that a risk-based variance approach is appropriate. Specifically, we do not have the authority to require the NRC or NRC Agreement States to implement the risk-based variance approach for specific treatment technologies (such as incineration). Generators seeking authority to construct and operate a complex treatment process unit such as an incinerator can apply for a RCRA treatment permit under the current regulatory system. Therefore, a variance process would duplicate the current RCRA permitting program.

4. Implementation of the storage and treatment conditional exemption

a. Self-implementation. The storage and treatment conditional exemption is triggered by the claimant who generates and stores the waste. To be eligible for a conditional exemption for stored low-level mixed waste you must notify the Director of your claim for exemption of your storage unit containing low-level mixed waste and of your compliance with all the conditions in § 266.230. You do not need to wait for approval from the State or Region with jurisdiction over the RCRA mixed waste program. However, you must be able to demonstrate that your claim is accurate, that your waste is eligible, and that you meet the conditions and other requirements specified in this rule. The Director may use inspection and information collection authorities to verify whether your waste met the eligibility provisions, you are meeting the conditions, and you are complying with all of the requirements.

RCRA section 3008(a) gives the Director the authority to take enforcement actions when you fail to meet any of the provisions of the conditional exemption. The appropriate regulatory authority can take a direct enforcement action against you when you fail to meet a specific RCRA requirement for your waste under this conditional exemption such as the notification or recordkeeping requirement. When you lose your exemption for your waste due to failure to meet a condition of the exemption, your waste is no longer exempted and it becomes a RCRA hazardous waste. The appropriate regulatory authority can take enforcement action against you for managing a hazardous waste without complying with RCRA hazardous waste requirements. As is the case under current RCRA regulations, concerned citizens also can bring to the regulator's attention any circumstance that might aid the authorities in monitoring and enforcement efforts. A concerned citizen also may file a suit under RCRA section 7002 against a generator for failure to meet any of the provisions of the conditional exemption. Lastly, the Director can take actions using authority under section 7003 and section 3013 of RCRA, 42 U.S.C. 6973, when it is determined that there may be an imminent and substantial endangerment to human health or the environment.

Comments Regarding Self-Implementation

We received few comments on self-implementation. One commenter who supported our approach indicated it was a practical way to implement the exemption and consistent with other EPA exemption programs, such as the Military Munitions Rule. We agree. Another commenter objected to self-implementing rules as not protective, and suggested we clearly specify enforcement and penalty provisions. Our studies conclude that regulation by NRC or NRC Agreement States of low-level radioactive waste protects human health and the environment during storage and treatment. In addition, our approach requires reporting of any failure to comply with the conditions of the exemption and the automatic loss of the exemption. We note this is similar to the current system under RCRA in which we rely upon reporting requirements and inspections for oversight.

The Director continues to have authority to inspect or collect information to verify independently the safe management of stored exempt waste. If a licensee reclaims a lost exemption, any violation must be corrected prior to the reclaim of the exemption, and an explanation of steps taken to prevent recurrence must be described in the reclaim notification. The Director can impose additional requirements or conditions on a licensee reclaiming an exemption, if appropriate. If violations of conditions or requirements demonstrate repeated and serious failure to comply, the Director may revoke a claim or reclaim of the conditional exemption. We expect that revocation would be an unusual event.

b. Loss of the storage and treatment conditional exemption (§ 266.240). If you previously claimed a storage and treatment conditional exemption from hazardous waste regulations and then fail to meet a condition listed at § 266.230, we continued to require at § 266.240 that you report the specific condition to the Director, and the NRC or NRC Agreement State in writing by certified delivery within 30 days of

learning of the failure. Your report must be signed by your authorized representative certifying that the information is true, accurate, and complete. This report must include the condition(s) you failed to meet, a description of the LLMW and storage location at the facility; and the date(s) on which you failed to meet the condition(s). If the failure to meet any of the conditions may endanger human health or the environment, you must also immediately notify the Director orally (within 24 hours), and follow up with written notification within five days. Failures that may endanger human health or the environment include, but are not limited to, discharge of a CERCLA reportable quantity or other leaking or exploding tanks or containers, or detection of radionuclides or hazardous constituents in the leachate collection system of a storage area. If the failure may endanger human health or the environment, you must follow the provisions of your emergency plan. Note that failure to meet recordkeeping and other requirements may subject you to an enforcement action requiring compliance, fines and penalties, or both.

We also clarified in § 266.240(b) that the Director may terminate your conditional exemption or add conditions to your exemption for serious or repeated noncompliance with any requirement(s) of subpart N. This language had appeared under § 266.245(b) in the proposal.

Under § 266.240, your waste automatically loses the storage and treatment exemption when you fail to meet any of the conditions in § 266.230. If your stored waste no longer meets one or more of the exemption conditions, that waste will be fully regulated under RCRA Subtitle C as a hazardous waste. The conditions set forth in § 266.230 are important, in conjunction with your NRC license, to ensure that LLMW is properly managed to avoid potential adverse impact on human health or the environment. In addition, the Director may terminate your ability to claim a conditional exemption for your waste and storage unit, or require you to meet additional conditions to claim a conditional exemption, for serious or repeated noncompliance with any requirement(s) of subpart N. The potential loss of the exemption resulting from failure to meet a condition will provide a strong incentive to properly manage the waste.

Response to Comments on Loss of the Storage and Treatment Conditional Exemption

We heard from a number of commenters in response to our specific request on whether the conditional storage and treatment exemption should be lost when any of the LLW storage requirements of the NRC or NRC Agreement State license are not met, or only when violations have occurred which may result in an adverse health or environmental impact. Several of these commenters supported losing the storage and treatment exemption when any of the LLMW storage requirements of the NRC or NRC Agreement State license are violated. These commenters believed that such a provision was a strong incentive for ensuring that the waste was managed properly. One of these commenters also requested that we retain a broad list of exemption violations because a limited list effectively suggests regulatory compliance is unimportant. A different commenter urged us to define the exemption conditions as specifically as possible to improve enforceability.

The majority of commenters, however, opposed our proposal that the generator would lose the storage and treatment exemption when any of the conditions of the exemption were violated. These commenters asked that we increase our specificity and limit the loss of exemption to violations resulting in actual endangerment of human health or the environment. Many of these commenters were concerned that the storage and treatment conditional exemption could be lost due to relatively minor administrative violations. In addition, although one of these commenters agreed that generator requirements are necessary to demonstrate that the waste has been properly managed, others believed that the failure to comply with recordkeeping requirements does not represent an imminent threat to public health and safety.

We also heard from a number of commenters who believed that we should build upon this concept of not automatically terminating a storage and treatment exemption for failure to comply with all of the provisions of the NRC or NRC Agreement State license to preclude also the automatic termination of an exemption for failure to meet any of the conditions listed in § 266.230(a)–(g). These commenters believed that we should not revoke an exemption because there was a violation of a condition only. One of these commenters cited our own research, which indicated that NRC inspections would ensure protection of human health and the environment during the storage period.

These commenters raised a number of valid points. Specifically, we agree that generators should not lose their exemption because of violations of their NRC or NRC Agreement State licenses that do not bear directly on whether the waste is being managed protectively on a day-to-day basis. Also, we have defined the exemption conditions specifically to improve enforceability. We note that NRC or NRC Agreement States can also enforce if LLW is improperly stored.

We did not intend to create a system that would render waste ''hazardous'' even though it is being managed in conformance with all the substantive conditions that EPA found to be protective. Although the potential for immediate return to RCRA regulation is consistent with the Military Munitions Rule, and may be necessary in some instances, we believe that recordkeeping violations (such as maintaining paperwork on training certifications) that you could promptly remedy, should not result in automatically subjecting you to all applicable RCRA permitting requirements. We have modified the conditions of the exemption so that you do not lose the storage and treatment conditional exemption automatically for a violation of a recordkeeping requirement associated either with your NRC or NRC Agreement State license, or today's rule. However, recordkeeping is important. Violations will subject you to enforcement, and repeated and serious violation of recordkeeping or other requirements could result in revocation of your claim or reclaim of a storage and treatment conditional exemption.

Finally, many commenters also suggested a 30-day time period (or other period of time as agreed to by the agency) to reestablish compliance before a generator risks losing the exemption. The commenters noted that failure to meet exemption conditions subjects the waste generator to enforcement actions from the regulatory agency having jurisdiction. Many of these commenters stated that the NRC or NRC Agreement State regulations or license conditions in effect during this time period should be sufficient to ensure protection of human health and the environment. Two of these commenters said this 30-day time period (or another time period agreed to by EPA) and the opportunity to reestablish regulatory compliance should be allowed even in situations where noncompliance results in endangering human health or the environment. We disagree; however, facilities have other options for

reclaiming the storage and treatment conditional exemption as soon as practicable.

As we discussed above, we modified the list of conditions so that only those provisions that we believe pertain directly to safe management of the waste are included. As a result of these changes, the storage and treatment conditional exemption will not be lost automatically for failure to meet a recordkeeping requirement (unless the Director determines that it indicates a serious or recurring problem or decides to revoke the reclaimed exemption under § 266.245[b]). We have concluded the conditions are, however, the minimum necessary to ensure that LLMW will be properly managed. We believe that the threat of losing the exemption for failure to meet any one of the conditions listed at § 266.230 will provide a strong incentive to properly manage the waste. We note that if you lose the storage and treatment exemption, the affected waste would return to the RCRA system as hazardous waste, and you would have 90 days (or up to 270 days if you are a small quantity generator) to accumulate the waste before it must be either shipped off-site for treatment and disposal or stored in a RCRA permitted storage unit. You could also reclaim your storage and treatment exemption, as long as you again meet the conditions in § 266.230 and submit the required reclaim notification.

c. If you lose your storage and treatment exemption can it be reclaimed? (§ 266.245). This conditional exemption final rule creates a process for the claim of a storage and treatment exemption, for the loss of the exemption in § 266.240, and for reclaim of the exemption in § 266.245. The storage and treatment exemption is automatically lost at the time of noncompliance with a condition. The Director does not need to take action to revoke the exemption. However, you may reclaim a lost conditional exemption if you again meet the conditions in § 266.230. You must send notification of the loss of the storage and treatment exemption due to a failure to meet a condition before you can reclaim the exemption. To reclaim, you must send the Director a notice by certified delivery that you are reclaiming the exemption. Your notice must be signed by your authorized representative certifying that the information contained in your reclaim notice is true, accurate, and complete. In your notice you must do the following:

- Explain the circumstances of the failure;
- Certify that you have corrected each failure that caused you to lose the exemption and that the waste again meets all conditions as of the date you specify;
- Describe plans you have implemented listing specific steps you have taken to ensure that the conditions are met in the future; and
- Include any other information you want the Director to consider when reviewing your notice reclaiming the exemption.

The storage and treatment exemption is automatically restored if you reclaim the exemption and meet these conditions. However, the Director may terminate a reclaimed conditional exemption if he finds that your claim is inappropriate based on factors including, but not limited to, the following: you have failed to correct the problem; you explained the circumstances of the failure unsatisfactorily; or you failed to implement a plan with steps to prevent another failure to meet the conditions of § 266.230. In reviewing a reclaimed conditional exemption under this section, the Director may add conditions to the exemption to ensure waste management during storage and treatment of the LLMW will protect human health and the environment. The language of the final rule has been reworded slightly for clarity, but is very similar to the proposal.

Comments Received on Reclaiming a Storage and Treatment Exemption

Many of the commenters who addressed the issue of reclaiming a storage and treatment exemption suggested that we provide a 30-day period during which a failure to meet a condition could be corrected without loss of the exemption. A small number of commenters suggested we impose a 90-day waiting period before a lost exemption could be reclaimed. One reason given for this waiting period was to allow regulators time to review documentation and conduct inspections before reinstating the exemption. A few commenters stated that the exemption should be maintained unless the violations endanger public health and safety. Another commenter stated the reclaimed exemption should apply both automatically and retroactively from the date of the loss. Yet another commenter stated that a licensee who loses a conditional exemption should not be allowed to reclaim it, and that the rule should contain heavy penalties for failure to meet one or more of the conditions.

Based on our studies of NRC storage requirements coupled with the conditions we have specified, we find that LLMW will be safely managed as LLW. We believe that because the reinstatement is available, it is appropriate that a licensee who fails to meet a condition is required not only to correct the failure, but also to implement procedures that would prevent such a failure from recurring. A large quantity generator of hazardous waste generally has 90 days to ship waste to a treatment or disposal facility before a permit for storage is required. This time period should provide sufficient time to correct most violations of the conditions. We have also indicated that the Director may revoke the reclaimed exemption if he finds the reclaim to be inappropriate. In addition, the Director may add conditions which must be met for a reclaimed exemption if deemed necessary to protect human health and the environment. Thus, we believe that the approach we have developed here, which allows EPA to devote its attention to facilities that raise particular concerns (for example, through inspections following the receipt of a reclaim notification), is protective, and more appropriate, than a scheme that would impose a 90-day waiting period on all facilities reclaiming the exemption. Such a scheme would make it very difficult for the generator to obtain reinstatement before becoming subject to the requirement to obtain a RCRA permit—a result that is unnecessary and undesirable since the NRC scheme is protective without a RCRA permit, and since EPA does not anticipate that it would typically choose to expend the resources to inspect and review reclaim requests during the proposed 90-day period. After the failure has been discovered by the generator or an inspector, but before a reclaimed exemption is in place, the generator may be subject to an enforcement action requiring compliance, or monetary sanctions, or both for violations that occur as a result of the loss of the exemption.

We also disagree with the commenter who stated that a licensee who loses a conditional exemption should not be allowed to reclaim it. Safeguards provided by NRC or NRC Agreement State oversight, coupled with the reclaim process we have outlined will provide both appropriate enforcement and a mechanism to correct any failure of the conditions. We believe these safeguards will deter noncompliance and will ensure that any violations are quickly corrected.

d. Recordkeeping requirements for the storage and treatment exemption (§ 266.250).

An important part of assuring that a generator is complying with the

conditions in today's rule is mandating the generator perform quarterly inspections of the units and drums or containers storing exempted waste, as well as conduct an inventory of the waste to prevent loss or other mismanagement. You must keep records of these activities to assure the Director of consistent compliance with exemption conditions. The annual inventory records, coupled with records of wastes placed in storage and records of shipments for treatment or disposal, will enable an inspector or other regulator to view a complete file of all conditionally exempt LLMW stored.

In our proposal, we used language similar to § 266.230 in § 266.250. Our intent was to ensure the availability of a complete record for inspectors to account for all stored conditionally exempt LLMW. Because this language appeared in two places in the proposal—§§ 266.230(f) and 266.250—it caused confusion. In the final rule we have eliminated the redundancy and combined all requirements relating to recordkeeping in § 266.250. Generators are responsible for demonstrating that the conditions have been and are being met, and must retain the necessary records to substantiate that claim. Violations of recordkeeping or other requirements could subject you to penalties and enforcement actions and, if violations are repeated and serious, could result in the revocation of your storage and treatment conditional exemption claim.

Comments Received on Recordkeeping for the Storage and Treatment Exemption

A few commenters addressed the types of records we are requiring. One commenter recommended we delete this section because NRC and Agreement States already have requirements for inventory and records management, objected that the frequency may conflict with keeping occupational exposures low, and requested an explanation for three-year record retention if not required by NRC. In response, we are retaining § 266.250 because these records relate to conditionally exempt waste which can only be identified through these records. We have clarified that the frequency of inventory is annual, thus minimizing the potential for occupational exposure. The rule requires record retention for three years after disposal of the waste because this is the general standard for RCRA record retention. In the absence of the conditional exemption (for example, if you lose the exemption), the waste would have to be managed under RCRA Subtitle C and records relating to the waste need to be available. Note that in some instances, NRC may require record retention for longer periods, in which case the records must be retained for the time specified by NRC requirements under 10 CFR part 20 (or NRC Agreement State requirements). NRC requirements always apply.

e. Return to RCRA of LLMW no longer eligible for the storage and treatment exemption (§ 266.255). For LLMW containing short-lived radionuclides, the storage and treatment conditional exemption will be in effect only until the radionuclide in the mixed waste has decayed to a point that it is no longer subject to NRC license requirements. After the decay-in-storage process is completed, the waste becomes subject to RCRA Subtitle C requirements. Under § 266.255 of the final rule, your waste is no longer eligible for the conditional exemption when one of two things occurs: (a) When ''your LLMW has met the requirements of your NRC or NRC Agreement State license for decay-in-storage and can be disposed of as non-radioactive waste * * * '' or (b) when ''your conditionally exempt LLMW, which has been generated and stored under a single NRC or NRC Agreement State license, is removed from storage. * * * However, your waste may be eligible for the transportation and disposal conditional exemption at § 266.305.'' In the first instance, our intent with this language is to clarify the applicability of the conditional exemption during a decay-in-storage time period and identify when RCRA Subtitle C jurisdiction resumes. In the second instance, we seek to make clear that all RCRA regulatory requirements apply during transport to a treatment or disposal facility, unless the waste qualifies for the transportation and disposal exemption at § 266.305.

i. How does the storage and treatment exemption facilitate decay-in-storage? NRC generally allows research, medical, and other facilities to store low-level wastes containing radionuclides with half-lives of less than 65 days (or more under an amended license) until 10 half-lives have elapsed, and the radiation emitted from the unshielded surface of the waste (as measured with an appropriate monitoring equipment) is indistinguishable from background levels. This process is known as decay-in-storage. Our final rule facilitates decay-in-storage by allowing LLMW with short-lived radionuclides to remain in storage until it is indistinguishable from background levels of radioactivity. The time allowed for LLW decay-in-storage is based on the radionuclides (and their half-lives) specified in a low-level waste generator's NRC license. Such management of LLW reduces worker exposures to radionuclides since workers are not exposed to wastes in containers during preparation or shipment to treatment and disposal facilities. Once the specified radionuclide decay has occurred, the waste may be disposed of as non-radioactive waste after you ensure that all radioactive material labels are rendered unrecognizable. (See 10 CFR 35.92 and 10 CFR 20.2001.) On that date, your waste is subject to hazardous waste regulation under the relevant sections of 40 CFR parts 260–271, and the time period for accumulation of a hazardous waste as specified in 40 CFR 262.34 begins.

ii. Change from proposed language. This language is essentially unchanged from the proposed storage and treatment exemption with the exception of the reference to ''under a single NRC or NRC Agreement State license,'' where the proposal stated ''when your waste is transported off-site.'' The change was incorporated here to be consistent with the eligibility requirements in § 266.225 of the final rule. We discuss the reason for this change in this preamble under section VI.A.1.

iii. Comments received on storage time limits and decay-in-storage. The comments we received on time limits for storage and decay-in-storage focused upon addressing the three areas on which we requested comment in the preamble. They are discussed below.

Determining RCRA Reentry for Radioactive Decayed Waste

In our proposal, we stated that ''We would appreciate comments regarding the standard to use for determining when the decayed waste would reenter RCRA Subtitle C management.'' (See 64 FR 63471.)

In both the proposed and final rule at § 266.255(a), the standard for determining RCRA reentry is when your LLMW has met the requirements of your NRC or NRC Agreement State license for decay-in-storage and can be disposed of as non-radioactive waste. At that point, management of any radionuclide in the waste is no longer required by the NRC or NRC Agreement State license. We picked this time frame because it is at this point that dual regulation ceases. It is also familiar to NRC licensees. Implementation will be clear, and will not conflict with NRC regulations.

A number of commenters wrote to us on this question. All but two supported our proposal, which indicated our reliance on NRC management during decay-in-storage, and transfer to EPA's RCRA Subtitle C oversight when decay is complete for the radionuclides

allowable under the NRC or NRC Agreement State license provisions. The two commenters who did not support the time frame we proposed were opposed to any conditional exemption of LLMW from RCRA Subtitle C management. These commenters believe that having waste exit the RCRA cradle-to-grave management system is contrary to the fundamentals of RCRA.

The other commenters agreed the transfer should occur on the date when NRC considers the decay complete—when the radionuclide with the longest half-life in a container has decayed as specified in the license (generally ten half-lives), and when the radiation emitted from the unshielded surface of the waste is not above background levels when measured by appropriate monitoring equipment. One commenter suggested that RCRA regulations should apply when the licensee removes the radiation label from the container—when the radiation emitted is indistinguishable from background levels—since RCRA reentry on this date would ensure continuous regulatory oversight.

We appreciate the support of the commenters who agree with our use of the NRC standard for decay-in-storage. Once the waste can be disposed of as non-radioactive waste, the waste is subject to hazardous waste regulation, and time periods for accumulation apply. We do not agree with the commenters who broadly oppose any conditional exemption because, as stated earlier, we have found that NRC or NRC Agreement State management of this waste during storage, coupled with the conditions we have specified in § 266.230, will ensure safe storage. In the final rule, we have retained the language in the proposal. We also believe that the lower cost of disposing of hazardous waste rather than LLMW, coupled with RCRA Subtitle C generator time limits (90–270 days depending on applicable regulations) will ensure timely waste management.

Appropriateness of Time Limit for Storage and Treatment Exemption

In our proposal, we made the following statement,

> We are considering whether a general storage exemption time limit should be imposed. A time limit may affect both facilities with untreatable legacy wastes and future treatment and disposal capacity. We invite comment on whether a time limit may be appropriate, and, if so, on what basis that time limit might be established. (See 64 FR 63471.)

The time limit for decay-in-storage is established by the terms of the NRC license. Under a decay-in-storage scenario, LLMW is no longer subject to NRC regulation when it has met the requirements of your license for decay-in-storage and can be disposed of as non-radioactive waste. On that date your waste is subject to hazardous waste regulation under the relevant sections of 40 CFR parts 260–271, and the time period for accumulation of a hazardous waste as specified in 40 CFR 262.34 begins. If the decayed waste still exhibits a RCRA hazardous waste characteristic or is a listed hazardous waste, then it must be shipped promptly off-site for treatment, if needed, to meet LDR treatment standards, and disposed of at a RCRA compliant facility. Thus, the RCRA accumulation time for a formerly mixed—now solely hazardous—waste begins when the radionuclide with the longest half-life in a container has decayed as specified in the license (generally ten half-lives), and the radiation emitted from the unshielded surface of the waste is not above background levels as measured by appropriate monitoring equipment as specified by NRC.

Some radionuclides take longer than 10 half-lives to decay to levels that are indistinguishable from background. If we limit the time for decay to ten half-lives only, then some portion of LLMW that is being stored may still emit radiation levels above background. To minimize radiation exposures, we have used ''and'' in § 266.255 to ensure that the LLMW does not emit radiation that is above background levels as measured by appropriate monitoring equipment. In the final rule language, we defer to the NRC practice for determining when the waste can be managed as non-radioactive and radioactive labels can be removed.

For those mixed wastes which are not undergoing decay-in-storage, the majority of commenters, including one State, agreed that the length of time that a LLMW could be stored under the conditional exemption should be that which is allowed for LLW under a facility's NRC or NRC Agreement State license, because of the significant management safeguards in place while the mixed waste is subject to NRC or NRC Agreement State regulations. Some commenters indicated that the cost of long-term storage and the rising trend in disposal costs would provide an incentive for generators to dispose of the waste in a timely manner to limit their overall costs for waste management. One commenter stated the following,

> ''Limiting the conditional exemption by an artificial clock will not improve on the safe and responsible management of LLMW under the NRC's jurisdiction. Instead it will * * * divert limited resources. * * * ''

A few commenters, including several States, provided suggestions for time limits we should impose for storage. They suggest lengths of time from one year, to two years, to three years, to an unspecified limit based upon the availability of treatment and disposal capacity, particularly for legacy wastes. Another commenter suggested a 5-year limit be imposed. An organization of state regulators commented that the quantity of waste accumulated is affected by the time period allowed and suggested that EPA set a limit either of time (3 years) or of capacity (volume). Other commenters suggested we set a capacity limitation of up to 10 kg because the disposal of small quantities of LLMW can be inefficient and extremely costly. Another commenter suggested that time limits be imposed through site-specific variances, in combination with capacity limitations and conditions for storage.

We also heard from two commenters, including one State, who believed a time limit was inappropriate because they opposed any exemption from RCRA Subtitle C regulations, and because NRC does not limit the volume of waste that can be stored on-site. A third commenter noted that RCRA prohibits storage of mixed wastes beyond specified periods, and no such storage prohibition exists in AEA-based regulations.

We agree with the large number of commenters who stated that we should adopt the NRC approach and not establish a limit on the length of time during which conditionally exempt LLMW may be stored. Their underlying argument was that the waste is safely stored if provisions of storage in the generator's NRC or NRC Agreement State license are being met. Our study of radioactive material storage indicated that NRC requires a licensee to maintain sufficient storage space to safely manage these wastes. For example, a generator must maintain sufficient aisle space for inspections and emergency response actions, and safeguards to limit exposures to ALARA. While NRC does not specifically limit the volume of waste stored, it does place a maximum on the radioactivity a licensee can manage. This provision of an NRC license serves to limit storage volumes. In addition, NRC discourages the accumulation of wastes that can be treated and/or disposed of. (See Generic Letter 81–38, ''Storage of Low-Level Radioactive Wastes at Power Reactor Sites.'') This fact, combined with cost considerations—that long term storage has associated management costs, and that the rising trend in disposal costs serves to encourage immediate rather

than delayed disposal—provides an incentive to generators to treat and dispose of wastes and avoid accumulation.

Another factor encouraging immediate disposal is the present uncertainty regarding access to existing LLRWDFs for many generators, given the present LLW Compact system. Our analyses of the protectiveness of the NRC regulatory framework for managing LLW indicated that LLMW would be stored in a manner that provided protection to human health and the environment equivalent to that based on EPA's RCRA Subtitle C system. To limit the storage time for wastes, including legacy wastes, further than time periods allowed by NRC or NRC Agreement States would subject generators to extraneous regulation without significantly reducing the likelihood of human health or environmental threats arising from stored LLMW. Commenters did not provide data which would assist us in establishing a non-arbitrary basis for choosing a time period for storage.

Potential Gap in Regulatory Coverage for Decayed Waste

In our proposal, we invited comment on whether waste being stored for decay under 10 CFR 20.2001(a)(2) and 10 CFR part 35 can be completely decayed while at the same time reenter RCRA Subtitle C without a gap in time during which the waste is not regulated as either hazardous or radioactive. We also requested that you do the following.

''* * * [I]ndicate in your comment what mixed wastes you generate that have radionuclides with activity levels which would not qualify for the conditional exemption we are proposing if it were based on whichever occurred first—ten half-lives of decay or not registering above background levels. Also indicate how this limitation would affect your management of the waste.'' (See 64 FR 63471.)

We note that an NRC licensee is not required to monitor the waste immediately after decay of 10 half-lives to determine if the radiation emitted is indistinguishable from background levels. Prior to monitoring, there may be an interval when the waste is hazardous only. However, it is only when the waste is monitored and the radiation emitted declared indistinguishable from background levels that the radioactive waste labels on each container must be removed. Our final rule indicates in § 266.255 that the waste would then be subject to RCRA Subtitle C jurisdiction for the hazardous wastes it contains.

A number of commenters responded to our request regarding a gap in coverage for decay-in-storage wastes. Some of them asserted there would be no gap if we relied on NRC provisions which require the generator to obliterate the container's radiation label once the container has been surveyed by appropriate monitoring equipment, and the radiation level is determined to be indistinguishable from background levels. One commenter noted that NRC requires documenting the release of the material from NRC regulation. Such documentation provides a date on which appropriate RCRA Subtitle C accumulation time periods would start.

Three commenters stated that if we did not conditionally exempt LLMW from the regulatory definition of hazardous waste, then no gap in coverage would occur. One of these commenters did note that for decay-in-storage waste, if we finalized a conditional exemption, ''RCRA control would be gained upon destruction of the radioactive label affixed on the waste * * *''

We appreciate hearing the suggestions of these commenters on eliminating a potential gap in regulation, and we agree that the date of the obliteration of the radioactive label (as the NRC requires) provides a documented and certain date for applying RCRA accumulation time periods.

iv. Effect on biennial reporting. Under 40 CFR 262.41, a generator who ships any hazardous waste off-site to a treatment, storage or disposal facility; or who treats, stores or disposes of hazardous waste on-site must submit a biennial report covering those wastes. Newly generated low-level mixed wastes that are exempted under this rule may be subject biennial reporting in accordance with 262.41 since, as generated, they are hazardous. Wastes only become nonhazardous when they meet the eligibility criteria and conditions of subpart N. Wastes that are exempted under today's storage and treatment exemption may, as with other RCRA wastes, again be subject to the reporting requirements of 262.41 if the waste is further managed outside the scope of the exemption. The Hazardous Waste Report Forms and Instructions booklet (EPA Form 8700–13 A/B) for the required reporting year explains who must file the hazardous waste report, and can be found at http://www.epa.gov/epaoswer/hazwaste/data/brs01/forms.html

Finally, it should be noted that today's final rule does not change the ability of states to impose reporting requirements above and beyond the Federal requirements, e.g., annual reporting or additional information about the generated, treated, recycled, or disposed hazardous waste.

f. Enforcement and enforcement policy. You, as the RCRA generator and NRC licensee, must be able to document that your claim for an exemption is accurate, that your waste is eligible, and that you meet the conditions and requirements specified in this rule. The Director may use inspection and information collection authorities to verify whether you have met and continue to meet the eligibility criteria, the requirements, and the conditions.

Facilities that fail to meet any of the conditions in § 266.230 for exemption will be subject to RCRA Subtitle C from the time that failure occurs. Utilities or other LLMW generators that claim the storage and treatment conditional exemption, but fail to store and/or treat the LLMW in compliance with the conditions of the exemption, no longer will be exempt from the applicable provisions of RCRA. Failure to meet requirements (in §§ 266.225 and 266.250) may result in an enforcement action to ensure compliance, penalties and fines. Moreover, imminent and substantial endangerment provisions under section 7003 of RCRA will continue to apply to conditionally exempt mixed waste as a safeguard since the waste remains a statutory solid and hazardous waste, so EPA can act in the unlikely event of circumstances which may pose a health or environmental threat. All RCRA statutory authorities that hinge on a waste's being a statutory solid and hazardous waste still apply (for example, sections 3007, 3013). We anticipate that most generators will be able to correct a failure to meet the conditions within a 90-day period and reclaim the exemption, thus avoiding any practical effect of losing the storage and treatment exemption and becoming subject to RCRA subtitle C regulation.

The storage exemption is based upon the NRC's regulatory framework governing the low-level radioactive waste component of LLMW. The NRC has a ''General Statement of Policy and Procedure for NRC Enforcement Actions'' (NUREG–1600) which states the NRC's policy regarding enforcement. This policy specifies significant consequences for violating NRC or license requirements and takes into consideration the specific circumstances of a particular case. For example, if a nuclear power plant violates an NRC license, or tie-down conditions of a license (see definition at the beginning of this preamble), the nuclear power plant (and the responsible person) may be subject to substantial civil and criminal penalties. Based on NRC regulations and this policy, licensed

facilities have a strong incentive to manage stored waste properly.

EPA Enforcement Policy Expiration

We intend to allow the mixed waste enforcement policy to expire on October 31, 2001. Several commenters have stated that EPA should extend the ''Policy on Enforcement of RCRA Section 3004(j) Storage Prohibition at Facilities Generating Mixed Radioactive-Hazardous Waste'' for sufficient time to allow authorized states to adopt the rule we are promulgating today. Commenters have expressed concern that EPA may rescind the mixed waste enforcement policy or that facilities may be subjected to ''unreasonable enforcement actions,'' including citizen suits, before they have the opportunity to obtain the exemption.

Commenters are correct that it may take some time for states (who choose to do so) to become authorized for this rule allowing a storage and treatment conditional exemption from RCRA Subtitle C for mixed waste. This rulemaking is intended to provide flexibility to generators of mixed waste where EPA requirements duplicate performance standards required by the NRC or NRC Agreement States. With the promulgation of this rule, EPA is expressing its view that facilities that comply with certain criteria can safely store mixed waste at NRC licensed facilities. Thus, the federal government is providing with this rule a potential option for mixed waste generators to store mixed wastes legally. We recognize that States are not required to become authorized to implement this rule. States may choose to be more stringent than the federal RCRA program. Although we do not intend at this time to extend the enforcement policy, we will monitor the implementation of today's final rule. Since States have generally followed EPA's lead on the enforcement policy, we anticipate a good number will choose to address dual regulation of mixed waste generators by acting on this rulemaking. States which do not adopt the rule may provide an enforcement policy within their states.

g. Storage unit closure. We received two comments indicating that our proposal may have generated some confusion as to how the conditional exemption would affect a facility's closure obligations for mixed waste storage units already regulated under RCRA. For example, one commenter requested that EPA develop a streamlined closure guidance for applicable facilities that are NRC licensed and can demonstrate an excellent compliance history. Another commenter specifically asked us to clarify that a generator would be exempt not only from the requirement to obtain a permit, but also from closure requirements. On reviewing these comments, we realized that we had not explicitly addressed closure of previously regulated units, although it was our intent to treat these units the same way the proposal would treat new units storing exempt waste, which is to say that they would be subject only to NRC decommissioning requirements, and not also to RCRA closure requirements. This is clear for new units, since the waste would not be hazardous and would not trigger closure requirements.

Thus, we are modifying the final rule to add § 266.260 to exclude LLMW storage units containing conditionally exempt waste from RCRA Subtitle C closure requirements. Without this modification, the rule could be read to require that facilities currently managing low-level mixed waste in permitted or interim status units to close these units because they no longer would be receiving hazardous waste. See 40 CFR 264.113 and 265.113. It was not our intent to require LLMW storage tanks or containers to be emptied and decontaminated to comply with RCRA closure requirements merely to be refilled with the same waste (now conditionally exempt). Such closure would run contrary to our conclusion that mixed waste managed under NRC regulation renders RCRA Subtitle C regulation, including closure, unnecessary. We also see no human health or environmental rationale for treating previously regulated units differently from new units in this regard. Finally, we believe that requiring RCRA closure before the unit can manage the same waste under NRC standards could unnecessarily increase worker exposures to the radionuclides. Therefore, a facility with a permitted tank or container that is storing only conditionally exempt LLMW, and has stored only LLMW prior to the effective date of this rule, is not subject to RCRA closure requirements, and may terminate their RCRA closure obligations as to that unit by modifying the facility permit under 40 CFR 270.42. Similarly, an interim status storage facility with a unit that has stored only LLMW will not be subject to RCRA closure requirement, and should amend the facility closure plan when the stored LLMW becomes conditionally exempt after the effective date of this rule. Without a modification to a facility's permit or closure plan, a facility would, arguably, still be required to close exempted units under RCRA. Of course, a storage unit that also stores non-exempt hazardous waste, either prior to or after the effective date of this rule, will remain subject to the closure requirements of 40 CFR 264.110 and 265.110 as applicable for areas storing the non-exempt hazardous waste.

These changes related to closure of a permitted or interim status storage unit, as described above, do not affect the applicability of corrective action authorities that the EPA or authorized State may have to address releases from these units (or from other solid waste management units at the facility). For these facilities, all hazardous wastes will be addressed either through the NRC requirements for decommissioning and decontamination (D&D) or through the use of our corrective action authorities. We note that current NRC guidance states that when an NRC inspector is preparing to inspect any facility that is undergoing decommissioning, the inspector should coordinate with the U.S. Environmental Protection Agency, or the appropriate State agency if the decommissioning involves hazardous waste. (See NRC Inspection Manual, Chapter 2602, 2602–05 General Guidance, 05.05 Inspection Coordination.) EPA commits to working with NRC to ensure that coordination with EPA or the appropriate state agency continues on these previously regulated units undergoing decommissioning.

B. Discussion and Response to Comments on Storage Background Studies

The storage and treatment provisions of our proposed and final rule are based on studies which we cited in the preamble to the proposal. These studies are available as supporting documents to provide background information to the public and to commenters on this rulemaking. These studies are ''Review of Waste Management Practices and Compliance History at Nuclear Power Plants and Other Entities that Generate Low-Level Mixed Waste.'' (April 12, 1999); and ''Comparison of the EPA's RCRA Requirements and the NRC's Licensing Requirements for the Treatment (In Tanks and Containers) and Storage of Low-Level Mixed Wastes at Nuclear Facilities'' (April 2001). To determine the protectiveness of NRC management requirements for LLMW, we researched the LLW storage and treatment provisions of NRC and material licenses, reviewed NRC compliance data on violations related to storage and treatment of LLW, and compared the regulatory framework of

EPA and NRC related to waste management. We found that safeguards were in place which would protect human health and the environment during storage and treatment of LLW and LLMW.

1. Review of NRC Licensing Requirements

We researched NRC's regulatory and licensing framework under which low-level radioactive waste (LLW), and therefore LLMW, is stored and treated by waste generators. We examined provisions concerning the on-site storage and treatment of LLW to assess whether these requirements are protective of human health and the environment with respect to preventing releases of hazardous constituents. We found that NRC and NRC Agreement States regulate licensees through the issuance of performance-based regulations, regulatory guides, generic communications (Generic Letters and Information Notices), and NUREGs. These documents work together to enable the NRC and Agreement States to ensure that nuclear power facilities and other licensees are operating in a safe manner. NRC uses these tools to guide licensees on how to meet the performance requirements in the regulations, and to impose an effective and enforceable regime to ensure protectiveness of the management of radioactivity.

For example, on November 10, 1981, NRC issued Generic Letter 81–38, ''Storage of Low-Level Radioactive Wastes at Power Reactor Sites,'' and enclosure, ''Radiological Safety Guidance for Onsite Contingency Storage Capacity.'' In this generic letter, NRC discussed its position on proposed increases in storage capacity for low-level wastes generated by normal reactor operation and maintenance, and stated that the safety of the proposed increase in capacity must be evaluated by the licensee under the provisions of 10 CFR 50.59. The NRC also attached a radiological safety guide to this letter. This guide was developed for the design and operation of interim contingency low-level waste storage facilities, and stated that necessary design features and administrative controls would be dictated by such factors as the waste form, concentrations of radioactive material in individual waste containers, a total amount of radioactivity to be stored, and retrievability of waste. NRC also noted that this guidance document should be used in the design, construction and operation of storage facilities, and that the NRC would judge the adequacy of 10 CFR 50.59 evaluations based on compliance with the guidance. (NRC also referenced IE Circular No. 80–19, dated August 22, 1980, as providing information on preparing 50.59 evaluations for changes to radioactive waste treatment systems.)

NRC regulations concerning the generation, storage, and treatment of LLW are performance-based (for example, no releases or leaks), whereas RCRA regulations are more prescriptive (where types of containers and waste management are specified to prevent leaks). Based on our review, the NRC-enforceable tie-down conditions found in individual licenses protect human health and the environment from exposure to hazardous wastes during storage comparable to RCRA regulatory requirements. A compilation of the NRC documents that we reviewed can be found in the docket. (See Ref. 3, EPA's compliance history review.)

2. Research on Compliance Records of NRC and NRC Agreement State Licensees

In addition to comparing NRC's storage requirements to EPA's, we researched compliance records related to NRC radiation controls for nuclear power plants and other licensees, to determine if there were storage-related releases or mismanagement of LLW. To provide a baseline for the comparison of NRC LLW violations, we queried two of EPA's generator information management systems—the Biennial Reporting System (BRS) and the Resource Conservation and Recovery Information System (RCRIS)—to obtain the number of RCRA violations.

Using BRS data for 1995, 18,497 facilities were identified as having generated hazardous waste (including small quantity generators). These records were merged with the information from RCRIS, and then sorted by RCRIS violation area codes. The violations were sorted by group (generator, other, treatment, and transporter) and by state. Based on this process, we identified a total of 4,547 violations by a total of 1,352 facilities (or 7.3% of the 18,497 facilities). Of the 4,547 violations, 3,355 resulted from noncompliance with the generator requirements (manifesting, recordkeeping, time-in-storage, reporting, etc.); of the 3,355 generator violations, 142 involved mixed waste.

To review the NRC facility compliance records, we reviewed a number of enforcement reports for both NRC-enforced and Agreement State-enforced licensing programs. (See IV.B.1. for a summary of reports reviewed.) The number of violations reported (on a percentage basis) by NRC for both nuclear power reactors (directly licensed by NRC) and material licensees (generally licensed by NRC Agreement States) compares favorably with the percentage of violations reported by EPA. Fines, penalties, and other consequences assessed by NRC and NRC Agreement States serve to deter violations. Based upon the compliance data, the industries' record is good and will serve to protect human health and the environment. In addition, the record suggests that there will be relatively few instances of violations of conditions leading exempt LLMW to become hazardous. We conclude that regulation under Subtitle C is unlikely to improve that record significantly. For further information on applicable NRC regulations refer to 10 CFR part 20 subpart I. Information regarding NRC's regulations, or guidance documents may be obtained by either contacting the NRC Public Document Room, at 11555 Rockville Pike, Room 0–1F21, Rockville, MD 20852 (301–415–4737 or 800–397–4209, Monday through Friday, 7:30 a.m. to 4:15 p.m.), or by visiting NRC's Internet web page at *http://www.nrc.gov.*

3. Comparison of Regulatory and Management Requirements of EPA and NRC

We compared NRC documents used in license preparation with the permitting framework established under RCRA. The technical design and operating standards of the NRC licensing program meet or exceed RCRA standards in virtually all respects, though there were differences in certain procedural requirements and in areas unrelated to actual releases of hazardous waste from storage. Based on our review, we do not believe these differences undermine protection of human health and the environment, or that the super-imposition of RCRA specific standards significantly increases protection. (See Ref. 4, EPA's comparison of EPA and NRC storage and treatment requirements.)

Relevant NRC licensing criteria are in the docket for the NPRM, and also may be obtained by contacting the NRC public document room at 301–415–4737, or accessing the NRC web site at *http://www.nrc.gov.* These criteria, while designed primarily to minimize radiation risk, also address risk posed by byproduct material in general, including hazardous constituents. Because of the unique nature of mixed wastes, migration of hazardous constituents does not occur except in the presence of radionuclides. Therefore, activities performed by a licensee to safely store or address the release of the radioactivity of mixed waste will also result in the safe storage

of the chemical components of the LLMW matrix. The applicability of NRC licensing standards to mixed waste in storage is the major reason for our finding that, under specified conditions, it is not necessary to also subject these wastes to RCRA storage regulation also.

4. Conclusions Based on Our Studies

We reviewed the requirements of NRC licenses, looked into the compliance records of NRC and NRC Agreement State licensees, and compared the regulatory and waste management requirements of EPA and NRC. Based on these studies, we conclude that NRC regulatory and licensing requirements will effectively control risks from hazardous constituents as well as radioactive material. We found that there are NRC regulatory safeguards in place which will apply during the storage and treatment of conditionally-exempt LLMW in tanks and containers. Therefore, because NRC and NRC Agreement State controls effectively address the mismanagement of LLMW, RCRA Subtitle C regulation is not necessary for those wastes. As the court explained in *Military Toxics Project* v. *EPA,* 146 F.3d 948 (D.C. Cir. 1998), ''where a waste might pose a hazard only under limited management scenarios, and other regulatory programs already address such scenarios, EPA is not required to classify a waste as hazardous waste subject to regulation under Subtitle C.'' We find that NRC and NRC Agreement State regulations governing LLW address scenarios where LLMW may pose a hazard.

5. Comments Received on Our Studies

We received several comments related to the studies we completed prior to our proposal. We heard from a number of commenters regarding our comparison of NRC's and EPA's regulatory and management requirements. A number of commenters concurred, indicating that the technical record for proposing the conditional exemption was compelling. Some of them stated that our comparison was comprehensive, and supported our rulemaking proposal.

Others commenting on the comparison encouraged us to conduct additional research regarding whether a single regulatory framework provides sufficient protection to safeguard human health and the environment. Some of these commenters were concerned about NRC monitoring for radiation but not chemical releases. They also wondered if NRC has ''sufficient expertise to properly deal with many of the issues related to storage and disposal of hazardous materials.'' Another commenter suggested that we require a minimum secondary containment volume for stored liquid LLMW. This commenter wanted us to define requirements for segregating chemically incompatible wastes, and thought that quarterly inspections were not protective and should be re-evaluated. Another commenter cited a 1986 chemical accident at a uranium conversion facility as evidence that NRC management of chemical hazards is deficient.

We disagree with those commenters who believe that the conditional exemption we proposed is not protective of human health and the environment because of NRC's focus on radiation. Our thorough studies do not support these concerns. Because exempted LLMW is mixed, the same management practices that address concerns for containment of radionuclides will also address concerns for the containment of the hazardous constituent. For example, NRC requires that chemically incompatible wastes be segregated to prevent the release of not only radionuclides, but also hazardous constituents. In another example, secondary containment for radionuclide release accomplishes the containment of hazardous constituents at the same time. Further, if, or when, a chemical release should occur, radionuclides are also released. Radiation release detection as required by the license will simultaneously alert personnel of a release of the chemical matrix in which the radionuclides exist. Therefore, management practices including treatment, primary and secondary containment, inspections, emergency responses, and others, that reduce the risk of radionuclide release will also mitigate the release of hazardous constituents. In summary, the expertise required to manage LLW is very similar to that necessary to manage hazardous waste. The NRC management framework provides protection for the hazardous constituents contained in mixed waste. (Note that 10 CFR 61.56 includes many features related to the physical and chemical characteristics of the waste.) As we indicated in our studies, minor differences exist between NRC's and EPA's regulatory frameworks (including inspection frequencies); the latter is more prescriptive and the former more performance based. However, taken together, the systems are equivalent. Both prevent releases, expeditiously address releases that may occur, avoid exposures, and protect human health and the environment.

We also disagree with commenters who believe our evaluation of the NRC framework was incomplete (i.e., that additional research was necessary to determine the sufficiency of a single regulatory framework). Rather, we agree with those commenters whose review concluded that our comparison was comprehensive. Based on our previous discussion, and on the written record we reviewed, we do not believe that additional research is necessary, or would yield information contrary to the conclusions we reached as a result of our studies.

In order to ensure that the hazardous portion of LLMW receives special management attention, we have made final the conditions in § 266.230 that address both personnel training in chemical waste management and hazardous materials incidents response, and emergency planning comparable to RCRA.

One commenter's reference to a 1986 radiation accident is not compelling evidence to support delaying this rule. Firstly, the date cited for the incident does not take into account guidance or operating procedures addressing such events at facilities which NRC has subsequently developed to prevent such accidents. Two examples of NRC's attempt to address problems with facilities as they arise are the NRC document NUREG–0933, ''A Prioritization of Generic Safety Issues,'' which provides priority rankings to resolve safety issues that have a significant potential for reducing risk, and NUREG–1601, ''Chemical Process Safety at Fuel Cycle Facilities, August 1997, which specifically addresses the handling of chemicals such as the one involved in the 1986 accident. Secondly, our review of waste management practices at NRC and NRC Agreement state licensed facilities in recent years, demonstrates an excellent record of safety, even when compared to hazardous waste management under RCRA. Thirdly, the accident cited by the commenter was not a waste management accident, but a chemical processing accident (allegedly caused by negligence). Finally, a single example of an accident that occurred 15 years ago does not lead us to conclude that the two regulatory schemes do not provide equivalent protection.

VII. How Are the Final Transportation and Disposal Provisions Different From the Proposal?

The final rule contains a number of language changes to respond to comments, and to make the storage and treatment exemption, and transportation and disposal exemption more consistent with each other. However, the final rule maintains conditional exemptions for

storage and treatment, and transportation and disposal. The changes to our proposal for transportation and disposal are highlighted below, and are discussed in greater detail in Section VIII of this preamble.

Streamlined Language

In the final rule we have streamlined our discussion of what the transportation and disposal conditional exemptions do and what the eligibility requirements are (§ 266.305 and § 266.310, respectively). These changes were made for clarity, and do not represent a substantive modification.

Specification Related to Containers

The language we used in the proposal was not clear as it related to the types of containers that must be used prior to placing the exempted waste in a disposal cell. We have specified in the final language that the container must be: a carbon steel drum, an alternative container with containment performance in the disposal environment equivalent to a carbon steel drum, or a high integrity container as defined by NRC. We made this clarification in § 266.340.

Notification

The proposed rule required you to notify multiple regulators and the LLRWDF during implementation of the conditional exemption. We proposed that you notify three separate regulators with various waste information. In addition, we also proposed that you notify the same agencies of any change in information presented in the initial notification, including a claim for the exemption of any waste stream not identified in the initial notification. In response to public comments, we streamlined the requirement of notifying the regulators. In the final rule, you must notify your RCRA regulatory agency. However, you are not required to notify the RCRA regulatory authority at the state where the LLRWDF resides, or NRC or NRC Agreement states that licensed the LLRWDF as proposed. In addition, we simplified the notification so that it is a one-time notice in order to identify who is claiming the exemption. As a result, you are no longer required to provide information such as the process that generated the waste, or the volume of the waste. You are also not required to notify your RCRA regulatory agency of changes from initial notice.

We modified slightly the proposed shipment-specific notice to a LLRWDF. It now incorporates a couple of elements that were previously in the notice to regulatory agencies (treatment standard verification and a signature requirement). We also added a statement indicating that the exempted waste must be placed in a container for disposal.

In the proposed rule, we proposed that you notify your RCRA regulatory agency in writing within 30 days of learning of your failure to satisfy any of the conditions and RCRA requirements under the conditional exemption. In response to comments, the final rule does not require reporting of noncompliance with paper work and administrative types of RCRA requirements such as notification and recordkeeping. However, we do require reporting of noncompliance with conditions in § 266.315.

Recordkeeping Requirements

We removed the proposed recordkeeping requirements associated with the notice of change to the regulatory agency, since this notification is not required in the final rule. We revised the duration you must keep your exempted waste manifest records from ''until closure of the disposal facility or closure of your facility'' to reliance on the existing NRC or NRC Agreement State requirement. We also revised your recordkeeping duration for the notice to the LLRWDF from ''until closure of the disposal facility or closure of your facility'' to ''for three years after the exempted waste is sent for disposal.''

Point of Exemption

The point at which a waste meeting land disposal restriction (LDR) treatment standards is conditionally exempted from RCRA regulatory requirements remains unchanged from the proposal. However, we changed one of the elements that described the point of exemption (§ 266.330[b]) from ''receiving return receipts from the regulators'' to ''receiving return receipts from the LLRWDF.''

Loss of Exemption

In the final rule, we do not require maintaining records or providing notice as conditions of keeping the exemption. Notice or recordkeeping becomes a RCRA regulatory requirement instead. Failure to meet either a recordkeeping, or a notice requirement will not result in the automatic loss of the exemption of the waste. However, the Director may terminate the conditional exemption for your waste or add additional conditions to the exemption for serious or repeated noncompliance with any of the RCRA requirements of Subpart N. In addition, such a failure may subject you to an enforcement action requiring compliance, monetary sanctions, or both.

In another change, we specified minimum reporting requirements in § 266.355(a) when you report the loss of an exemption.

Finally, in § 266.355(a) we added the provision of orally notifying your RCRA regulatory agency within 24 hours of discovery of failure to meet any of the conditions if the failure may endanger human health or the environment. This oral notice must be followed up with a written notice within 5 days.

Reclaiming the Transportation and Disposal Exemption

In the final rule, we have slightly modified the procedure you must follow to reclaim an exemption for your waste. You are required to send a notice to your RCRA regulatory agency, by certified delivery with return receipt requested, that you are reclaiming the exemption for your waste. In the final rule, the reclaimed exemption becomes effective after you receive the return receipt from this reclaim notice. This procedure is different from the proposal, which allowed the reclaimed exemption to become effective as soon as you meet the reclaim requirements for your waste. In addition, you may initiate the reclaim process for your waste only after you have received the return receipt from your RCRA regulatory agency confirming that it has received your notice that you have lost the exemption for your waste. We made these change in response to comments received on our question on whether there should be a waiting period prior to a reclaimed exemption becoming effective.

VIII. Discussion and Response to Major Comments on the Transportation and Disposal Conditional Exemption

In today's rule, we are finalizing a conditional exemption from RCRA Subtitle C regulation for hazardous wastes containing LLW and/or NARM that are transported and disposed of subject to NRC or NRC Agreement State regulation. Eligible wastes (LLMW or Eligible NARM) that are managed in accordance with the conditions under § 266.315 are exempt from the RCRA regulatory definition of hazardous waste. The conditional exemption takes effect once specified actions have occurred. You then may manage your wastes as you would solely radioactive wastes. Since the point of exemption takes place when a waste is placed on a transportation vehicle destined for a low-level radioactive waste disposal facility (LLRWDF) for disposal, the exempted waste need not comply with RCRA Subtitle C transport and disposal

requirements. This conditional exemption acknowledges the protection provided by NRC and NRC Agreement States regulations for the manifest, transportation, and disposal of the radioactive portion of the eligible waste.

The conditions for the transportation and disposal exemption are listed in § 266.315, and include the following:

- The wastes must meet LDR treatment standards;
- Waste shipments from those of you who are not already subject to NRC or NRC Agreement State manifest and transportation regulation must comply with the NRC (or NRC Agreement State) manifest and transportation regulations;
- The wastes must be disposed of at a LLRWDF licensed by NRC (or Agreement State); and
- The wastes must be disposed of in containers that meet specified minimum requirements.

Your waste automatically loses its transportation and disposal exemption if you failed to meet any of the conditions specified in § 266.315. You must notify your RCRA regulatory agency when your waste loses its exemption. You may be subject to an enforcement action requiring compliance, monetary sanctions, or both for any violations that occur as a result of this loss of exemption. You may reclaim your transportation and disposal conditional exemption for your waste if it again meets the conditions specified in § 266.315, and you notify your RCRA regulatory agency that you are reclaiming the exemption for your waste.

A. What Is the Basis of the Transportation and Disposal Conditional Exemption?

We determined that a conditional exemption from RCRA Subtitle C regulation for the transportation and disposal of eligible waste is appropriate because we concluded that management of eligible waste under NRC and NRC Agreement State regulations coupled with the additional conditions set forth in today's rule provide a comparable level of protection for the RCRA constituents. We reached this conclusion after a thorough analysis comparing NRC transportation and disposal requirements to RCRA hazardous waste regulations. We believe that this analysis demonstrates that NRC regulations effectively protect human health and the environment for the circumstances allowed under today's conditional exemption. Thus, we do not believe the waste managed under these conditions should be subject to Subtitle C, since Subtitle C controls are not necessary to protect human health and the environment. For a complete explanation of the legal basis for establishing a conditional exemption under RCRA see the preamble to the Military Munition Rule at 62 FR 6636 (February 12, 1997). See also *MTP* vs *EPA,* 146 F3rd 948 (D.C. Cir.1998) upholding EPA authority to establish conditional exemptions under RCRA.

We received comments both supporting and opposing the general approach of our proposed rule. Forty-nine commenters—including generators, some states, RCRA facilities, members of the public, and the NRC—supported our overall approach. They believed that our proposal was sound and would provide the important and necessary regulatory protection and flexibility for the management of the eligible waste.

Of the commenters that questioned our proposed rule, some stated that NRC's regulations and requirements were established to protect against radioactive hazards and not against hazards posed by RCRA hazardous waste. Therefore, they believed that it is not appropriate to rely on NRC regulations for protection against chemical hazards. We agree that NRC and NRC Agreement State regulations were not established for the primary purpose of protecting against risks posed by RCRA hazardous waste. However, we disagree with the conclusion that it is not appropriate to rely on these regulations for protection against hazards posed by RCRA wastes.

Specifically, concerning the transportation of hazardous material, EPA and NRC have expressly adopted DOT regulations governing the transportation of hazardous material. The Department of Transportation (DOT) packaging and transportation requirements for a LW provide adequate protection against chemical hazard during the transportation of an eligible waste meeting the LDR treatment standards. DOT Hazardous Material Regulations (HMR; 49 CFR parts 100 through199) contain requirements for transporting hazardous materials. DOT HMR contains packaging, labeling, documenting, placarding, and other requirements for transporting hazardous material. The DOT hazard classification system includes materials that are explosive, flammable, reactive, toxic, infectious, corrosive, radioactive, and gases. Hazardous materials subject to the HMR must, at a minimum, be packaged in strong tight containers that can safely survive transportation incidents. EPA has adopted DOT regulations governing the transportation of hazardous materials to protect human health and the environment in the transportation of hazardous waste. NRC LLW packaging and transportation regulations have also adopted DOT regulations for transporting radioactive material. Under this conditional exemption, the exempted waste is required to meet the LDR treatment standards and therefore no longer exhibits the flammable, corrosive, and reactive characteristics. As a result, the transportation packaging requirement for the exempted waste do not need to consider these hazards. The remaining hazard of concern of the exempted waste is the toxicity of the waste. We consulted with DOT who stated, and we agreed, that the transportation packaging requirement for the transportation of the LLW is adequate for the protection against the toxic hazard that would remain in the waste that has met LDR treatment standards. (See Ref. 19, Discussion with DOT on mixed waste transportation.) Therefore, the exempted waste, once meeting the LDR treatment standards, will be properly managed if it is packaged and transported as a LLW. For these reasons, we concluded that packaging and transportation controls that apply to a LLW are adequate, appropriate, and will ensure safe management of the exempted waste during transportation.

Concerning tracking of hazardous waste, the exempted waste (a radioactive waste) is subject to NRC or NRC Agreement State equivalent manifest regulations. We conducted a detailed comparison between RCRA and NRC manifest regulations that track the movement of the exempted waste (See Ref. 12, Comparison of NRC and EPA's Waste Tracking.) We determined that NRC's waste tracking regulations are at least as stringent as RCRA regulations. Most notably, both RCRA and NRC manifests were developed to be consistent with the DOT shipping paper regulations at 49 CFR 172.200. Therefore, RCRA and NRC manifests share many basic elements, including closed-loop notification and tracking, exception reporting, and mandatory retention of manifests. However, the NRC manifest regulations exceed the RCRA Subtitle C manifest regulations in several areas, such as requiring longer manifest retention times in certain cases and specifying more stringent schedules for generators to investigate shipments for which they have not received the LLRWDF's acknowledgment of receipt. Therefore, we believe that NRC regulations for tracking low-level waste meet our needs to ensure that the exempted waste arrives at the appropriate licensed LLRWDF, and that NRC provides adequate mechanisms for

Federal or state oversight of the waste shipments.

We also reviewed NRC regulations (10 CFR part 61) and the practices of low-level waste disposal facilities to determine if they provide levels of human health and environmental protection comparable to RCRA Subtitle C permitted disposal facility requirements. (See proposal F–1999–ML2P–FFFFF, Ref. 7, Technical assessment of LLRWDFs.) This analysis included the elements of siting, disposal cell engineering and design, and management control. Our assessment indicates that NRC regulations for disposal facilities provide protection comparable to that provided by RCRA Subtitle C regulations, particularly given that we are requiring that the RCRA hazardous constituents be treated to LDR treatment standards and that the waste be placed in certain types of containers prior to disposal. More detailed discussion of this technical analysis can be found in section VIII.G. of today's document.

In summary, our analysis of NRC transportation and disposal regulations leads us to conclude that the NRC regulations coupled with a few additional conditions provide adequate protection of human health and the environment, and that regulation under RCRA Subtitle C is not necessary. The fact that NRC regulations were designed primarily for the purpose of protecting against radioactive waste is largely irrelevant since the regulations are designed to ensure protective transporting, tracking, and containment of the waste, which will protect against chemical hazards as well as radiation hazards.

B. What Wastes Are Eligible for the Transportation and Disposal Conditional Exemption?

As we proposed it, the transportation and disposal conditional exemption would apply only to LLMW that meets the waste acceptance criteria of a LLRWDF and Eligible NARM. A LLMW is a RCRA hazardous waste as defined in 40 CFR part 261, containing a low-level radioactive waste as defined in 10 CFR 61.2. A table identifying the types of RCRA hazardous waste commonly found in LLMW is provided as background material in the RCRA Docket (See Ref. 10, RCRA Hazardous Constituents and Waste Codes.) In the final rule, Eligible NARM is defined as a NARM waste that contains RCRA hazardous waste, and meets the waste acceptance criteria of, and is allowed by State NARM regulations to be disposed at a LLRWDF licensed in accordance with 10 CFR 61 or NRC Agreement State equivalent regulations.

NARM is defined by its origin of generation rather than by the level of its radioactivity. The manner in which NARM waste is managed depends on the radioactive content of the material. In most cases, NARM waste is radiologically similar to low-level radioactive waste. Because today's rule applies to LLMW, we are extending the exemption to NARM only when its radioactive content is comparable to LLW and is managed as such. A LLRWDF is required to establish waste acceptance criteria as part of its license requirements to ensure protection of human health and the environment. The waste acceptance criteria are derived from the performance criteria of the disposal facility and ensure that only those wastes that can be accepted and properly managed at the LLRWDFs are accepted. Therefore, we are requiring that in order to be eligible for the transportation and disposal exemption, your Eligible NARM waste must meet the waste acceptance criteria of a LLRWDF and therefore will be properly managed.

In the proposed rule, we solicited comments on the applicability of this conditional exemption to hazardous waste contaminated with NARM. We received comments that both supported and questioned the inclusion of NARM contaminated with RCRA hazardous waste for the exemption. Those who supported including this waste stated that we should not exclude NARM waste solely because it is not regulated under the Atomic Energy Act (AEA). They also stated that the source of generation of the radioactive material, under which NARM is defined, should not have bearing on whether the NRC or Agreement State equivalent regulations provide a sufficient level of protection for the waste. They stated that NARM is similar to LLW, and should be eligible for the conditional exemption.

Those who opposed the inclusion believe that the NRC has no regulatory authority over NARM. We note that although NRC does not have regulatory authority over NARM, the States may regulate this material. Some states have laws and regulations in place for managing this material. We note that all three states that license the existing LLRWDFs have such authority. In the case of Non-NRC Agreement states, where the NRC implements the radioactive material management regulations, the States may enact additional laws and regulations to regulate NARM. However, to ensure that there will not be regulatory gap under this conditional exemption for NARM, we are specifying that you can claim this exemption for your Eligible NARM waste and dispose of the NARM waste at a LLRWDF only if state laws and regulations governing that LLRWDF allow the disposal of NARM waste. In addition, as discussed earlier the waste acceptance criteria of a LLRWDF will ensure that any NARM accepted at a LLRWDF will meet the licensing requirement and will be properly managed. Therefore, there is no regulatory gap in managing NARM waste even though the NRC does not have regulatory authority over this waste.

We received two comments requesting that DOE waste be excluded from the exemption due to oversight concerns. Rather than excluding DOE waste from eligibility for the conditional exemption, we fashioned the conditional exemption to ensure external oversight of DOE waste. First, to be exempt, eligible waste must be disposed of at an NRC or NRC Agreement State licensed LLRWDF. Second, DOE must follow the NRC or NRC Agreement State equivalent manifest and transportation regulations. These conditions ensure that any exempted DOE wastes are under the oversight of an external regulatory agency. (As explained below, in the case of the manifest and transportation provisions, the agency would be the RCRA regulatory agency, by virtue of a condition contained in the final rule.)

C. What Conditions Must You Meet for Your Waste To Qualify for and Maintain the Transportation and Disposal Conditional Exemption?

1. Land Disposal Restriction Treatment Standards

As we proposed, eligible waste must meet the RCRA Land Disposal Restriction (LDR) treatment standards before it is transported and disposed of as an exempted waste. You can find the RCRA LDR treatment standards in 40 CFR part 268, subpart D.

In HSWA, Congress prohibited the land disposal of hazardous waste unless the waste is treated to minimize threats to human health and the environment. The statute required EPA to establish treatment standards that will substantially diminish the toxicity or mobility of hazardous waste to minimize short and long-term threats to human health and the environment. We have developed a series of treatment standards for hazardous waste based on the best demonstrated available technology (BDAT) for treating the waste. The LDR treatment standards ensure that the organic constituents are

destroyed or substantially reduced and the mobility of the toxic metals are stabilized to minimize threats to human health and the environment. In contrast, the approach to waste treatment for a radioactive waste is stabilization and containment while the waste undergoes radioactive decay. We could not confidently conclude that NRC waste stabilization requirements for radioactive waste assure long term protection of human health and the environment from all types of RCRA hazardous waste. Therefore, we have decided to maintain the LDR treatment requirements as a condition of the exemption.

In some instances, a RCRA hazardous waste becomes a nonhazardous waste when it is treated to the designated LDR treatment standards. These situations involve treatment standards for ignitable, corrosive, and reactive characteristic wastes, and most standards for the toxic characteristic wastes. Some of the treatment standards for hazardous debris also allow the treated debris to be managed as a nonhazardous waste. In addition, there are other processes (e.g. delisting under 40 CFR 260.20 and 260.22) through which a RCRA hazardous waste can become a nonhazardous waste. Under these situations when your LLMW or Eligible NARM waste is no longer a RCRA hazardous waste, you do not need to claim the transportation and disposal conditional exemption in order to manage and/or dispose of the resulting waste as a LLW or a NARM waste. The resulting waste would be regulated as a radioactive waste only. You should contact your RCRA regulatory agency if you have questions concerning the treatment standards or the processes which may allow your LLMW or Eligible NARM waste to be regulated as non-hazardous waste.

You must continue to comply with all other provisions associated with the LDR treatment regulations (e.g. sampling and analysis to determine compliance with LDR treatment standards or certifying such compliance). Additionally, recognizing the public's concern over potential radiation exposure from mixed waste testing we developed a mixed waste testing guidance. The guidance was developed in close coordination with NRC, and is titled ''Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste.'' You can find this guidance at EPA's mixed waste web site at (*www.epa.gov/radiation/mixed-waste/*). The primary purpose of the guidance document is to assist you in the characterization of mixed waste in accordance with RCRA regulations, while keeping radiation exposure as low as reasonably achievable (ALARA). The guidance document emphasizes flexibility in the RCRA testing requirements to incorporate the ALARA concept.

In the proposed rule, we solicited comments on whether we should exclude LDR Phase IV alternative soil treatment standards from the LDR treatment standards that eligible waste must meet for you to claim the conditional exemption. The majority of the commenters supported including the alternative soil treatment standard as part of the LDR treatment standards which must be met to qualify for the conditional exemption. The Association of State and Territorial Solid Waste Management Officials commented that this decision should rest with the States in which the disposal will occur.

We believe that it is appropriate to include the alternative soil treatment standards under this conditional exemption. We promulgated the alternative soil treatment standards under the LDR Phase IV Rule found at § 268.49 to provide flexibility for remediation activities. The LDR Phase IV Rule can be found at [63 FR 28602–28622, May 26, 1998]. In the LDR Phase IV Rule, we determined that the technology-based treatment standard (90 percent reduction capped by 10 times the Universal Treatment Standards) for contaminated soil is sufficiently stringent to satisfy the core requirement of RCRA § 3004(m) that short and long-term threats to human health and the environment are minimized. The alternative soil treatment standards also consider the need to encourage remediation of contaminated soil which involves excavation and treatment of the soil. In the case of this conditional exemption, wastes treated to LDR treatment standards, including the alternative soil treatment standards, must be placed in a container for disposal. We believe the soil treatment and waste container requirement, in conjunction with the protection provided by the radioactive waste disposal facility, ensure protection to human health and the environment. We note that states may impose more stringent requirements when they adopt this rule. In conclusion, the final rule does not exclude the alternative soil treatment standard in § 268.49 from the LDR treatment standard in today's transportation and disposal conditional exemption.

2. Manifest and Transportation

a. If you are subject to NRC or NRC Agreement State regulation: Today's final rule relies on NRC or NRC Agreement State manifest and transportation regulations (which also refer to DOT regulations at 49 CFR parts 100–199) to control the manifesting and transportation of the exempted waste shipment. If your exempted waste streams are already subject to these externally regulated manifest and transportation requirements, you have no additional transportation and manifest requirements or conditions under today's rule. The Agency believes it is unnecessary to impose additional requirements on you because your waste shipments already are subject to NRC, NRC Agreement State, or DOT enforcement actions if you failed to meet the manifest or transportation regulations.

b. If you are not directly subject to NRC or NRC Agreement State regulation: Today's rule imposes a condition on facilities, such as DOE facilities, whose radioactive waste shipments are not directly subject to NRC or NRC Agreement State manifest and transportation requirements. The condition requires these facilities to comply with the manifest requirements at 10 CFR part 20 (or NRC Agreement State equivalent regulations), and/or the transportation requirements under 10 CFR part 71 (or NRC Agreement State equivalent regulations). This condition is necessary because such facilities are not subject to enforcement actions by NRC or an NRC Agreement State in the event they fail to meet the NRC or NRC Agreement State specified requirements. Hence, as an alternative to NRC or NRC Agreement State oversight, when such a facility fails to meet this condition in today's rule, the facility's waste will automatically lose its exemption. This facility may become subject to an EPA (or RCRA-authorized State) enforcement action requiring compliance, monetary sanctions, or both, thus providing an external enforcement mechanism that would otherwise not exist. This approach addresses concerns regarding shipment of conditionally exempted waste by facilities who are not already subject to NRC or NRC Agreement State manifest and transportation regulatory requirements. This condition also ensures the consistent application of the manifest and transportation requirements for the exempted waste.

This exemption is contingent upon waste disposal in an NRC, or NRC Agreement State, licensed LLRWDF. Therefore, it is important that a mechanism be in place to track all exempted waste in transit and confirm that the exempted waste arrives at the appropriate disposal facility. This exemption also relies on the added

protection provided by the NRC, or NRC Agreement State regulations for the transportation of the exempted waste. We do not believe this condition will impose an unreasonable burden on these facilities who are not directly subject to NRC or NRC Agreement State manifest and transportation requirements. Therefore, we are maintaining this condition as proposed.

Some commenters expressed a broad concern that reliance on the LLW manifest would not provide carriers or emergency responders with the information they need to respond to transportation incidents involving the exempted waste. We note that even though the LLW manifest does not contain specific information of the chemical constituent of the exempted waste, the emergency response procedures for an incident involving radioactive material are very rigorous and similar to the procedures used in responding to an incident involving a chemical material. In addition, an NRC or NRC Agreement State LLW manifest also contains an emergency contact telephone number allowing the emergency responder to contact the shipper for additional information on the waste contained in the particular shipment if needed.

It is important to note that the exempted waste will be treated to meet the RCRA LDR treatment standards. In particular, the acute hazards related to the reactivity, corrosivity, and ignitability characteristics of the RCRA characteristic waste that are of primary concern during transportation, will be eliminated when a waste is treated to LDR treatment standards. The chronic toxicity of the toxic characteristic and listed wastes will also be greatly reduced. Also, the exempt waste will not contain free liquids, which will significantly enhance containment of the waste.

A professional emergency responder is trained to manage a wide variety of transportation incidents. The responders will approach radioactive wastes with the same care and caution as they would use in approaching a LLMW. Radioactive constituents generally have similar exposure pathways to humans (e.g. dermal contact, ingestion, or inhalation) as RCRA hazardous constituents do. Therefore, emergency response personnel would take the same precautions as they would for a RCRA hazardous waste such as wearing protective clothing and carrying supplied air. Also, because radioactive wastes present a risk based on the responder's proximity to the waste package, emergency responders also will limit their proximity and time near the waste as they would for a RCRA hazardous waste. Therefore, we believe the concern raised by these commenters is properly addressed due to the nature of the waste and the procedures and precautions that will be taken for responding to a radioactive waste transportation incident.

3. Container Requirement

Today's rule requires placing the exempted waste in a container before disposal. The container must be one of the three types specified under § 266.340:

- A carbon steel drum;
- A container with equivalent containerization performance in the disposal environment as a carbon steel drum; or
- A high integrity container as defined by NRC.

It is your responsibility to make the appropriate arrangements and ensure that the exempted waste is placed in a container for disposal.

The proposed rule did not require specific types of containers, but instead specified that the container ''cannot be cardboard or fiberboard boxes.'' However, a commenter indicated that they did not believe that this standard was prescriptive enough to ensure appropriate containment of the waste. We agree with this comment. In response, we have specified in the final rule the acceptable types of containers which are consistent with the technical analysis performed during the rulemaking process.

In the proposed rule, we noted that both EPA and NRC disposal facility requirements provide similar features to isolate waste from its disposal environment. An NRC disposal facility is not required to have a synthetic liner, whereas a RCRA facility is. To ensure an equally protective disposal environment for purposes of the conditional exemption, we compared the performance of the RCRA hazardous waste landfill synthetic liner to the performance of a carbon steel drum and a high integrity container (as defined by NRC). We found that the performance of these specific containment devices are comparable for the purpose of retaining the integrity of the waste in the disposal cell (See Ref. 7, Technical Evaluation.) The Agency based its proposed container requirement on the landfill liner and container comparison analysis, but now realizes that the proposed regulatory language could allow disposal alternatives that do not provide the same protections as we intended. The proposal language specified that the container cannot be cardboard or fiberboard boxes. Some commenters noted that the description would allow paper boxes or wooden crates that are also unacceptable.

The final requirement is still flexible in that it allows for alternatives to carbon steel drums as long as the container used achieves equivalent performance. We also allow the use of high integrity containers (HICs) since they must pass a series of rigorous tests as specified by NRC to demonstrate that they will retain their structural integrity for 300 years or more. These HICs are more often used by LLRWDFs to stabilize and contain wastes with higher radioactivity than LLMW. We decided to codify HICs for purposes of this conditional exemption because they provide containment equivalent to carbon steel drums.

4. Waste Disposal Destination

Today's final rule requires that the exempted waste must be disposed of only at a LLRWDF licensed and regulated by NRC, or an NRC Agreement State, in accordance with 10 CFR part 61 or NRC Agreement State equivalent regulations. It is your responsibility to make the appropriate arrangements to dispose of the exempted waste at the designated LLRWDF. This provision is unchanged from the proposal.

Some commenters stated that NRC shallow land burial facilities are ''designed to fail,'' and cited past failures at such facilities. Our investigation indicated that the facilities cited by the commenters were designed and operated prior to NRC's codification of regulations for LLRWDFs in 1982 at 10 CFR part 61. NRC promulgated these requirements in response to the failures and problems cited by the commenters. Since that time, the NRC and the NRC Agreement States have worked aggressively with the LLRWDF licensees to ensure that the LLRWDFs meet current regulatory requirements and additional NRC technical guidance specified in technical position papers. In particular, the NRC waste form technical position paper ''Technical Position on Waste Form (Revision 1)'' contains specific criteria on how the waste should be stabilized prior to disposal at LLRWDF. The waste form criteria are generally incorporated into the LLRWDF's license as waste acceptance criteria. In addition, since 1982, NRC regulation has prohibited disposal of liquid waste. Based on EPA's analysis of NRC and NRC Agreement State LLRWDFs, EPA concludes that LLMW treated to LDR standards will be safely managed at such facilities. (See discussion in VIII. G.)

Prior to our proposed rule, States expressed concern about DOE's self-regulating status for managing the radioactive material. Generally, States that regulate radioactive material have no regulatory oversight authority for DOE's radioactive material. However, NRC and NRC Agreement States have regulatory authority over commercial and other non-self regulating federal facilities that manage radioactive materials. Therefore, in today's rule, we are exempting only those wastes disposed of at an LLRWDF that is licensed and regulated by NRC or an NRC Agreement State. This approach will ensure that all exempted waste (radioactive waste) remains under an external regulatory framework and enforcement authority. DOE may take advantage of the transportation and disposal exemption if it disposes of its exempted waste in LLRWDFs licensed and regulated by NRC or an NRC Agreement State. This approach addresses the States' concern and allows DOE to take advantage of the exemption. All of the comments on this provision supported the Agency's proposed approach.

D. What Other Provisions Must You Meet?

The Agency is finalizing the RCRA notification and recordkeeping requirements for this rule. These RCRA requirements are obligations that you must meet at all times. If you fail to meet these RCRA requirements, you must take prompt actions to return to compliance with these RCRA requirements. Your waste will not automatically lose the transportation and disposal conditional exemption if you fail to meet these RCRA requirements for your waste. However, your RCRA regulatory agency may terminate a conditional exemption or add additional conditions to an exemption for serious or repeated noncompliance with any of the RCRA requirements of subpart N. In addition, you could be subject to an enforcement action requiring compliance, monetary sanctions, or both under RCRA 3008(a) enforcement authority for failure to comply with any of the RCRA requirement(s) of subpart N for your waste.

1. Notification

Today's rule requires you to provide a one time notice to your RCRA regulatory agency under § 266.345(a) prior to the initial shipment of an exempted waste from your facility to a LLRWDF to claim the transportation and disposal conditional exemption. The notification must include your facility name, address, telephone number, and your RCRA ID number. You need not notify your RCRA regulatory agency again for subsequent shipments of the same or a different waste stream from your facility. The purpose of this notice is to identify to the RCRA regulatory agency those of you who are claiming the conditional exemption.

Today's rule also requires you to notify the LLRWDF receiving your exempted waste before each shipment of your waste. Your notification must provide the information required under § 266.345(b) which includes:

- A statement that you have claimed the exemption for your waste;
- A statement that the waste meets all applicable LDR treatment standards;
- A statement identifying your facility name, address, and RCRA ID number;
- All applicable RCRA waste codes for the waste before the waste was exempted;
- A statement that the exempted waste must be placed in a container for disposal;
- The manifest number of the shipment that will contain the exempted waste; and
- A certification that the information provided is true, accurate and complete.

We expect that most, although not all, of the information on this notice to a LLRWDF will remain the same from shipment to shipment, especially when the same waste stream is continuously being shipped for disposal. Therefore, a previous notice to the LLRWDF can easily be updated and used as the new notice. Alternatively, you also can choose to develop your own standard notice to an LLRWDF with unchanging information already filled in.

The notice in § 266.345(b) serves several important purposes. First, it will allow the LLRWDF receiving the exempted waste to identify the waste and place it in a container for disposal. Since the exempted waste would be managed and identified as any other radioactive waste after the point of exemption (See discussion in section VIII. E.), a mechanism is needed to allow the identification of the exempted waste at the LLRWDF. The manifest number of a shipment that contains exempted waste will enable such identification. In the case of the standard NRC Uniform Low-Level Radioactive Waste Manifest Form 541, the manifest number appears in block number 2.

Second, the notice informs the LLRWDF that it is receiving a conditionally exempted waste, and allows it to take actions that it may deem appropriate. A LLRWDF's willingness to receive the exempted waste is essential in obtaining the benefit of this rule. During the proposal stage of this rulemaking, owners and operators of LLRWDFs indicated that they want to know when they would be receiving an exempted waste. (See Ref. 9, Notes of meeting with LLRWDFs.) They want to be able to decide, on an operational basis, whether to take precautionary actions such as screening for specific constituents in a shipment or screening for LDR compliance. The information regarding the RCRA hazardous waste codes of the waste stream before it was exempted will allow the LLRWDFs to be aware of the content of the waste and take proactive steps as they deem appropriate. In addition, you may only ship the exempted waste to an LLRWDF after you have received the return receipt from the LLRWDF confirming that it has received your notice. This provision ensures that the LLRWDF will have advance notice of the arrival of the exempted waste so that the LLRWDF can ensure that the exempted waste is handled accordingly.

Finally, this notice, in conjunction with the recordkeeping requirement, also will provide information to facilitate inspection and other oversight activities. You are required to keep records of this notice, and make these records available during inspection or upon request.

The notification requirements in today's final rule differ from the proposed rule in several respects:

- Simplified initial notices to regulatory agencies when claiming an exemption;
- Added notification elements in the notice to LLRWDF to ensure proper handling of the exempted waste at the LLRWDF;
- Removed notices to regulatory agencies of changes in information submitted in the initial notice;
- Removed notices to regulatory agencies of failure to satisfy recordkeeping or notification requirements; and
- Changed status of the notice to your RCRA regulatory agency when claiming the conditional exemption from a condition of the rule to a RCRA requirement. (See loss of exemption discussion in Sec. VIII.F.2.)

We received comments that both supported and opposed the multiple notifications to the regulators and the LLRWDFs. Some commenters stated that proper notification to the LLRWDF will allow the LLRWDF to prepare for receipt of waste and ensure compliance.

To address the concern raised regarding multiple notices, we evaluated the proposed notification requirements. We found difficulties and burdens associated with multiple notifications and broad notification requirements. Consequently, we simplified the notification requirement by reducing the number of regulators you must notify and the amount of information you must provide. In the final rule, you need only notify the RCRA regulatory authority. You are no longer required to provide information such as the exempted waste volume and the process that generated the waste. The re-notification of changes from the initial notice to the regulator also is not required. The intention of the proposed notices to the regulators was to identify those of you who are claiming the conditional exemption, and to provide information on the exempted waste. The revised notice to your RCRA regulatory agency in today's final rule will continue to serve these purposes while reducing unnecessary burden. The notice will identify those of you who are claiming the conditional exemption. In addition, even though the notice will not contain information about the exempted waste, the regulatory agency can still obtain information related to the waste or other aspect of the exemption from you when necessary because you are required to keep records related to the exemption.

We also evaluated the notice to the LLRWDF. We modified this shipment-by-shipment notification requirement to ensure that the exempted waste will be properly managed at the LLRWDF. We slightly expanded this notice requirement to include the following additional information: a statement that you have claimed the exemption; a statement that the waste meets the LDR treatment standards; and a statement that the exempted waste must be placed in a container for disposal. This information can be included in a standard form letter. Therefore, we do not expect that the additional information requested will increase the reporting burden. This notice to a LLRWDF will continue to include identification information including your facility and the RCRA waste code of the waste stream. We believe this notification requirement will provide the mechanism to ensure proper handling of the exempted waste at the LLRWDF.

Notices to your RCRA regulatory authority and the LLRWDF, in conjunction with the recordkeeping requirement, will provide adequate information to facilitate inspection and enforcement activities. You are required to maintain records of the exempted waste, and must make records available during an inspection or upon request. (See Sec. VIII. D. 2. of this preamble.) The state regulator who licensed the LLRWDF can obtain information about the exempted waste from the RCRA regulatory authority where the LLRWDF is located or where you are located.

In the proposed rule, we required you to report to your RCRA regulatory agency when you fail to satisfy administrative and paper work requirements, such as notification or recordkeeping. Many commenters said that this provision is unnecessarily broad and should focus only on reporting noncompliance that would endanger human health and the environment. The commenters believed that broader reporting requirements would impose an undue burden on the regulated community and provide information of little or no value to the regulators. We considered this comment and agree that reporting noncompliance with administrative requirements (such as recordkeeping) is unnecessary. We believe that human health and the environment will be protected provided facilities meet the technical conditions and standards necessary to ensure safe management of the waste. However, you are required to make the appropriate notifications, maintain records, and ensure that records are accurate and complete. You also are required to make these records available either during an inspection or as requested. If the records are found to be incomplete or inaccurate, then you are subject to an enforcement action requiring compliance, monetary sanctions, or both. These penalties can be significant. Therefore, we believe that there is a strong incentive for you to satisfy the RCRA notification and recordkeeping requirements, and make the necessary corrections promptly. As a result, we no longer require you to report noncompliance with notice and recordkeeping requirements.

2. Recordkeeping

Today's rule includes recordkeeping provisions in § 266.350 as follows:

- Records in § 266.350(a) reference the existing RCRA recordkeeping requirements necessary to demonstrate compliance with the LDR treatment standards.
- Records in § 266.350(b), (c) and (d) are necessary to demonstrate compliance with the RCRA notification requirement and waste container condition of the conditional exemption.
- Records in § 266.350(d) are also necessary to document that exempted waste was disposed of at the designated disposal facility. It enables regulators to track and identify the shipment of low-level radioactive waste that contained exempted waste.
- Records in § 266.350(e) are necessary to document and demonstrate compliance with the manifest and transportation condition for the facilities who are not directly subject to NRC or NRC Agreement State manifest and transportation regulations.

These records will provide the regulatory agency with information during inspections to determine whether you are complying with all of the conditions and RCRA requirements of the rule. It is important that you maintain a complete and accurate set of the required records, and that you make them available when requested. The recordkeeping provision is now a RCRA requirement instead of a condition for the exemption. Your waste will not automatically lose the exemption if you fail to meet the recordkeeping requirements. However, you could be subject to an enforcement action requiring compliance, monetary sanctions, or both.

We received comments both supporting and questioning the proposed duration of the recordkeeping requirements. Specifically, some commenters voiced concern over requiring a generator or treater to retain records for the radioactive waste manifest and the notice to LLRWDF until closure of the LLRWDF or closure of the generator's or treater's facility. These commenters stated that such requirements are overly burdensome and inconsistent with existing regulations, and indicated that the proposed recordkeeping timeframes could result in record retention for decades after a waste was shipped. They pointed out that both NRC (10 CFR part 30) and EPA (40 CFR part 262) regulations require a generator or treater to retain records for only three years. In addition, they stated that 10 CFR 61 already requires a LLRWDF to maintain records of the LLW manifest until termination of the LLRWDF license activities.

We reexamine the proposed recordkeeping duration requirement and agreed with the commenters that it is not necessary for a generator or treater to maintain records beyond three years after the waste is sent for disposal. Therefore, the final rule requires the records be retained for three years. In the case of maintaining LLW records such as the LLW manifest, this time period is consistent with NRC regulations under 10 CFR part 20, or equivalent NRC Agreement State regulations which generally is also three

years for generators and treaters. For disposal facilities, the NRC manifest records are maintained by the facility until closure of the LLRWDF or closure of the generator's or treater's facility. Although not required by today's rule, we recommend and encourage LLRWDF's to similarly maintain their copy of the exempt-waste notices until facility closure since these records could be useful in the future for identifying the exempted waste that was disposed at the facility.

Today's recordkeeping requirement changed from the proposed rule as noted below.

- In the proposal we had required you to keep NRC manifest records until closure of the disposal facility or closure of your facility. In the final rule you only need to keep records of the NRC manifest for the time period required by NRC.
- In the proposal we had required you to keep your notices to LLRWDFs until closure of the disposal facility or closure of your facility. The final rule only requires you to keep the records for three years after the exempted waste is sent for disposal.
- The recordkeeping requirement is a RCRA requirement under the authority of sections 2002 and 3007 of RCRA instead of a condition of the rule. (See loss of exemption discussion in Sec. VIII.F.2.)
- You are not required to report noncompliance related to recordkeeping requirements. (See Sec. VIII.D.1. notification discussion.)
- The recordkeeping requirements associated with the re-notification to regulator of changes have been removed because this notice no longer exists. (See notification discussion in Sec. VIII.D.1.)

E. When Does the Transportation and Disposal Exemption Take Effect?

Today's rule conditionally exempts eligible waste from RCRA Subtitle C manifest, transportation, and disposal requirements because we found that RCRA Subtitle C regulation is not necessary if waste meeting LDR treatment standards and containerized prior to disposal is managed according to NRC manifest, transportation, and disposal requirements for the management of the radioactive component of the waste (See our technical evaluation, Ref. 7, and our comparison of NRC and EPA waste tracking, Ref. 12.) The Agency has chosen to exempt the waste from the RCRA regulatory definition of hazardous waste at the point where your waste meets LDR treatment standards; you have completed NRC or NRC Agreement State equivalent packaging, preparation for shipment, and manifest requirements; and you have placed the waste on a transportation vehicle destined for an LLRWDF licensed by NRC or an Agreement State. Once the exempted waste has been placed on a transportation vehicle for disposal, the waste may not be taken to other facilities for further management purposes. Stops during transportation to pick up additional wastes, or to transfer wastes (including radioactive waste transporters using their transfer facilities to consolidate radioactive waste shipments) are not considered ''further management.''

Thus when:

- Your eligible waste meets LDR treatment standards;
- You have received return receipts confirming that you have notified your RCRA regulatory agency and the receiving LLRWDF;
- You have completed the Packaging and Preparation for Shipment requirements for the eligible waste according to NRC Packaging and Transportation regulations found under 10 CFR part 71 (or NRC Agreement State equivalent regulations);
- You have manifested the treated waste according to NRC manifest regulations found under 10 CFR 20.2006 (or NRC Agreement State equivalent regulations); and
- You have placed the waste on a transportation vehicle destined for the receiving LLRWDF,

then the exempted waste may be transported as a LLW or NARM. Once properly containerized at the disposal facility, the exempted waste may also be disposed of as LLW or NARM.

We received comments describing complications if the point of exemption occurs when the waste has been placed on a truck destined for a disposal facility. The commenter indicated that facilities often use centralized waste staging areas to package, label, inspect, and manifest wastes in preparation for transportation. According to the commenter, placing the point of exemption after the waste is placed on the transportation vehicle would require meeting both RCRA hazardous waste and NRC radioactive waste packaging and labeling regulations instead of meeting just the NRC radioactive waste packaging and labeling regulations. However, this was not our intention because we found that the NRC or Agreement State packaging, preparation for shipment, and manifest requirements are adequate for the shipping and tracking of the treated waste. Therefore, we are clarifying that it is not necessary to package, label, and manifest the waste as RCRA hazardous waste when preparing the waste for transportation to disposal. The exemption will start at the moment waste is placed on the transportation vehicle if you claim and qualify for this conditional exemption.

Another commenter expressed concern over the proposed requirement that exempted waste not go to any other facility en route to the designated LLRWDF, other than to a transfer facility. The commenter stated that this requirement would not allow a transporter to pick up waste from more than one facility and would unnecessarily increase the shipping cost and waste shipping traffic. We agree with the commenter and are changing the final rule language to clarify that such stops are acceptable.

F. Implementation

1. How Will the Transportation and Disposal Conditional Exemption Be Implemented?

The transportation and disposal conditional exemption we are promulgating today will require no prior governmental approval or review of documentation before your waste exits RCRA Subtitle C regulations. This basic framework is consistent with other hazardous waste exemptions. It also is consistent with the LDR program. The LDR program allows a generator or treater to certify that their hazardous waste meets LDR treatment standards and qualifies for land disposal without prior governmental approval.

We are allowing this approach because we believe that there is no significant benefit to requiring approval for an exemption. Furthermore, the waste exiting RCRA Subtitle C requirements will continue to be managed under an alternate regulatory program (NRC or NRC Agreement State regulations) that provides appropriate protection for human health and the environment. This also is true for those of you who self-regulates under the AEA, because your waste also must be disposed of at an LLRWDF regulated by NRC or NRC Agreement State. Therefore, we conclude that under the proposed method, the waste will continue to be properly managed while the regulatory burden is reduced. In addition, such implementation has the following advantages:

- The exemption can take effect more quickly;
- It reduces your burden associated with acquiring the approval; and

• It does not impose a burden on the regulatory agency to review and approve the exemption.

However, this approach does not mean that the appropriate regulatory authority does not have a role in overseeing the conditional exemption. You must keep records of the exemption and make them available to the appropriate regulatory authority during inspection or upon request. The appropriate regulatory authority may conduct inspections, audit records, obtain samples, and perform any other information gathering activities authorized under RCRA, including under 3007, 42 U.S.C. 6927, to determine whether you are in compliance with all of the provisions of this exemption. Nothing in subpart N shall be interpreted or applied to restrict any inspection or enforcement authority under RCRA, 42 U.S.C. 6901, et seq.

RCRA 3008(a) gives the appropriate regulatory agency the authority to take enforcement actions when you fail to meet any of the provisions of the conditional exemption. The appropriate regulatory authority can take a direct enforcement action against you when you fail to meet a specific RCRA requirement for your waste under this conditional exemption such as the notification or recordkeeping requirement. When you lose your exemption for your waste due to failure to meet a condition of the exemption, your waste is no longer exempted and it becomes a RCRA hazardous waste. The appropriate regulatory authority can take enforcement action against you for managing a hazardous waste without complying with RCRA hazardous waste requirements. However, note that a loss of exemption can be reclaimed (see discussion in the following section). Depending on the situation that led to the loss of exemption, an exemption could be quickly reclaimed in order to avoid any significant consequences. Today's rule also does not change the ability of citizens to inform regulators of any circumstance that might aid in monitoring and enforcement efforts. A concerned citizen also may file a suit under RCRA 7002 against you for failure to meet any of the provisions of the conditional exemption. Lastly, the appropriate regulatory agency can take actions using authority under 7003 and 3013 of RCRA, 42 U.S.C. 6973, when it determines that there may be an imminent and substantial endangerment to human health or the environment.

2. Loss of Transportation and Disposal Conditional Exemption

Under today's final rule, any waste will automatically lose its transportation and disposal conditional exemption if you do not manage it in accordance with all of the conditions specified in § 266.315. Depending on which condition or conditions you failed to meet and the circumstances surrounding the failure, the affected waste could be a single drum, a number of drums, a treated waste stream containing specific waste codes, or a number of treated waste streams with specific waste codes. The exemption is lost at the time of noncompliance. The appropriate regulatory authority need not take action to remove the exemption. The conditions of the exemption are the technical conditions and standards that we have determined to be necessary to achieve proper management of the waste and ensure protection of human health and the environment. Therefore, we believe it is appropriate that a waste automatically lose its exemption if you do not manage it in accordance with these technical conditions and standards.

You must report to your RCRA regulatory agency when any of your waste loses its exemption. Your report must be in writing, by certified delivery, within 30 days of learning of the failure. In your report you must describe at a minimum: any specific condition(s) that you failed to meet for your waste, information (e.g. name, waste code, and quantity) regarding the waste stream that lost the exemption, and the date(s) on which the condition(s) were not met. The report will allow the appropriate regulatory agency to be aware of any noncompliance and to take appropriate actions, if necessary. The appropriate regulatory authority may request additional information from you to facilitate the investigation. If the failure to meet any of the conditions may endanger human health or the environment, then you also must report such failure to your RCRA regulatory agency orally within 24 hours of learning of the failure. A written notice must follow your oral notification within 5 days.

You also may lose the transportation and disposal conditional exemption for your waste for serious or repeated noncompliance with any of the RCRA requirement(s) (e.g. notification or recordkeeping) of Subpart N. In this situation, the appropriate regulatory authority may terminate your ability to claim the conditional exemption for your waste. The appropriate regulatory authority also may require you to meet additional conditions in order to claim a conditional exemption. This provision gives the appropriate regulatory authority the ability to revoke a conditional exemption from you if you have serious and repeated compliance problems related to the notification or reporting requirements.

When you lose the exemption for your waste, you may also be subject to an enforcement action requiring compliance, monetary sanctions, or both for any violation of RCRA Subtitle C regulations.

Today's loss of exemption provision changed from the proposed rule in several respects:

• In the final rule, notice to regulator and recordkeeping are RCRA requirements instead of conditions of the exemption. Noncompliance with these RCRA requirements will not result in automatic loss of exemption;

• You can lose your ability to claim a conditional exemption for serious or repeated noncompliance with any of the RCRA requirements (e.g. notice to regulator or recordkeeping) of Subpart N;

• We have specified minimum reporting requirements for reporting a failure to meet a condition; and

• We have added one reporting requirement stating that when a waste loses its exemption, if the failure to meet any of the conditions may endanger human health or the environment, you must orally notify EPA or the Director within 24 hours of discovery of failure and follow up with a written notice within 5 days.

We received comments that both supported and opposed the proposed loss of exemption provision. The commenters who supported the provision believed that an automatic loss of exemption was a strong incentive for ensuring that waste would be properly managed. However, the majority of comments expressed concern over losing the exemption due to relatively minor administrative violations such as incorrect spelling of a facility name.

Upon further evaluation, we believe that the commenters raised a valid issue. We recognize the undue difficulties and burdens associated with the automatic loss of exemption due to failure to comply with administrative requirements alone. In the proposed rule, the exemption conditions included both technical conditions and standards necessary to ensure safe management of the waste, and administrative type of requirements such as notification and recordkeeping. As proposed, when an exemption is lost due to failure to meet the administrative requirement alone, you would have to manage the waste as RCRA hazardous waste while correcting the infraction and then reclaim the exemption. However, the technical conditions and standards of the

conditional exemption necessary to ensure safe waste management would continue to be met. We believe that it is appropriate to impose the automatic loss of exemption when technical conditions and standards for safe management of the waste are not met and could by itself directly lead to impact to human health and the environment. However, we do not believe that automatic loss of exemption is warranted for errors related to administrative requirements, such as recordkeeping, which by themselves are unlikely to lead to environmental harm. We evaluated the proposed conditions and made modifications so that the administrative requirements, such as recordkeeping, are RCRA requirements instead of conditions of the exemption. The conditions as specified under 40 CFR 266.315 of today's rule are the technical conditions and standards necessary to maintain the exemption. We believe this is more consistent with the overall approach of today's rule, which is that eligible waste is not ''hazardous'' for Subtitle C purposes if properly managed. Although it is important that EPA be able to enforce paperwork violations, we do not think these violations alone support the conclusion that the waste becomes hazardous for Subtitle C purposes. As a result, the automatic loss of exemption will only apply to noncompliance with technical conditions and standards, and not to failure to meet the RCRA requirements of this rule such as recordkeeping.

Nevertheless, the notification and recordkeeping requirements serve an important function in the implementation of the conditional exemption. These RCRA requirements also play an important role in compliance determination. Therefore, we want to maintain a mechanism that will provide the appropriate regulatory authority with the ability to revoke the exemption for failure to comply with these RCRA requirements where necessary. In the final rule, the appropriate regulatory authority may terminate your ability to claim a transportation and disposal conditional exemption for your waste for serious and repeated noncompliance with the RCRA requirements of Subpart N. We do not expect this provision to be used casually. We view it as a means to ensure that you take the reporting and recordkeeping requirements seriously and that you comply with these RCRA requirements at all times. Revocation of the transportation and disposal conditional exemption would be effective after the Director takes this action and would only affect subsequent waste shipments.

We also received comments regarding the requirement to report noncompliance with the conditions and RCRA requirements of the rule. Two commenters urged us to consider requiring the facility to orally report a condition that endangers human health and the environment within 24 hours. We agree with the commenter and note that it is a standard RCRA requirement that an oral report, followed up with a written notice within five days, be made for situations that threaten human health and the environment. Therefore, we have modified the final rule to incorporate this provision.

3. Reclaiming the Transportation and Disposal Conditional Exemption

Under the final rule, any waste will automatically lose its exemption if it is not managed in accordance with the conditions under § 266.315. However, you may reclaim the exemption for your waste if it is again managed in accordance with all of the conditions under § 266.315. You may initiate the reclaim process for your waste only after you have received the return receipt from your RCRA regulatory agency confirming that it has received your loss of exemption notice that you have lost the exemption for your waste. When reclaiming a lost exemption, you must notify your RCRA regulatory agency that you are reclaiming the conditional exemption for your waste. In this reclaim notice, you must do the following:

- Explain the circumstance of each failure to meet a condition;
- Certify that each failure that caused the waste to lose the exemption has been corrected and that the waste again meets all of the conditions as of the date you specified; and
- Demonstrate that each failure is not likely to recur, listing the specific steps that you have implemented to ensure the conditions will be met.

You also may provide any other information that you want your RCRA regulatory agency to consider when it reviews your notice reclaiming the exemption.

We are requiring a notice to reclaim an exemption because the conditions of the exemption represent those technical conditions and standards which will ensure safe management of the waste. Therefore, we believe that it is important that you notify your RCRA regulatory agency of events that led to the loss of the exemption so that it can take steps, if necessary, to ensure that waste will be managed properly. The appropriate regulatory authority can review your records, collect additional information, or conduct site visits. This communication and information will allow your RCRA regulatory agency to work with you to correct the problems that led to the non-compliance with the conditions. The appropriate regulatory authority may add additional conditions, where appropriate, to the exemption to ensure proper management of the waste to protect human health and the environment.

The reclaimed transportation and disposal exemption becomes effective when you have received the return receipt confirming that your RCRA regulatory agency has received your reclaim notice. The return receipt can be a certified U.S. Postal receipt or a certified receipt from a mail delivery service. Additionally, as proposed, the appropriate regulatory authority may terminate a reclaimed conditional exemption if it finds that the claim is inappropriate.

Today's transportation and disposal exemption reclaim requirement is changed from the proposed rule in one area. We added a new requirement that you may initiate the reclaim process for your waste only after you have received the return receipt confirming that your RCRA regulatory agency has received your notice that you have lost the exemption for your waste. This provision is not required under the storage and treatment exemption. This slight variation is designed to ensure that a waste, for which the lost exemption is being reclaimed, will not be transported to a LLRWDF before your RCRA regulatory authority is made aware that you have lost the exemption for your waste.

We received comments on the issue of whether a transportation and disposal exemption could be reclaimed after it has been lost. Some commenters supported the proposed rule that allowed the exemption to be reclaimed. Some commenters noted that requiring notification to reclaim is burdensome and unnecessary. One commenter urged the Agency to disallow the reclaiming of an exemption.

In general, we believe that you should be allowed to reclaim a lost exemption. We believe that even a responsible generator or other waste handler may, on rare occasion, be in noncompliance with the conditions of the exemption. Because the consequence of the loss of the exemption for a waste is potentially the full imposition of the RCRA Subtitle C regulation, we believe a permanent loss of exemption would unduly penalize responsible generators and other waste handlers and downstream handlers. However, we want to

emphasize that failure to meet the conditions can result in RCRA enforcement actions, fines, penalties, and the permanent loss of exemption. Thus, the mechanism to discourage violation of the conditions is in place. Therefore, we are allowing you the opportunity to reclaim the exemption for its waste when the infraction has been corrected and is not likely to recur.

We note that other RCRA rules provide a similar provision for reclaiming a lost exemption. We established a conditional exemption from the RCRA transportation and storage requirements for persons that transport or store nonchemical waste military munitions in accordance with 40 CFR 266.203 or 266.205, respectively. Under that conditional exemption, we established procedures for persons to reclaim a lost transportation or storage exemption (see § 266.203[b] and § 266.205[c]). The final rule is consistent with the provisions of § 266.203 and § 266.205.

In addition, as stipulated in § 266.360(b), the appropriate regulatory authority may terminate a reclaimed exemption if warranted. This provision allows the appropriate regulatory authority to deal with repeat or serious offenders. Therefore, we believe that the final rule is adequately flexible to enable the appropriate regulatory authority to react to violations in a manner that is commensurate with the severity of the violation. The final rule not only ensures protection of the environment, but also motivates facilities to meet the exemption conditions.

In the proposed rule, we solicited comments as to whether we should impose a waiting period before the exemption could be reclaimed. We asked whether we should provide a 90-day waiting period before the reclaimed exemption is effective. We solicited input on whether a waiting period is necessary to allow time for the appropriate regulatory authority to review the reclaim notification, and to deal with repeat or serious offenders. The majority of the commenters believed that a 90-day waiting period was unnecessary. They believed that you should be able to reclaim the conditional exemption for your waste as soon as the noncompliance with the conditions is corrected with reasonable assurance that the noncompliance would not recur. Several commenters noted that further delay in reclaiming the exemption would serve no purpose and could potentially result in uncertain regulatory status and/or unreasonable enforcement action. Other commenters stated that the appropriate regulatory authority could conduct an inspection at any time and take actions if necessary. Some states believed that there should not be a binding time period for the review. Lastly, one commenter stated that without a waiting period, you would be motivated to correct the noncompliance that resulted in the loss of conditional exemption as quickly as possible in order to minimize penalties and return to exempt operations. However, several commenters indicated their support for a 90-day waiting period before allowing licensees to reclaim a lost transportation and disposal exemption so that there would be time to review documentation, conduct an inspection, and/or hold a public hearing before reinstating the exemption.

After considering the comments, we do not believe that it is necessary to require a waiting period before the exemption is reinstated if the violation has been corrected. This approach is generally consistent with the current RCRA regulatory program. For example, under the LDR program, hazardous waste generators or treaters can send the waste for disposal after self-certifying that the waste has met the LDR treatment standard without a waiting period.

Today's rule also provides the appropriate regulatory authority with flexibility regarding the amount of time it has to review a request to reclaim an exemption. It can, at any time, review the notification, request additional information, or conduct a site inspection to verify the validity of the reclaim or the purported successfulness of measures designed to prevent the recurrence of a failure. By not specifying a time period for review, we are providing regulators flexibility and the ability to evaluate any reclaim notice at any time and to focus their attention and limited resources as they deem most appropriate. This mechanism also avoids the implication that a reclaim is approved if the appropriate regulatory authority was not able to review the reclaim and respond before the end of the waiting period. We note that the appropriate regulatory authority will continue to maintain a broad range of inspection, and information collection authorities to ensure compliance with the exemption conditions under RCRA 3007, 42 U.S.C. 6927. Thus, the appropriate regulatory authority has the ability to conduct an inspection at any time, and can take enforcement actions, and assess fines and penalties if you are found to be in noncompliance with the reclaim requirements.

We believe that these requirements are sufficient for the appropriate regulatory authority to track compliance and conduct enforcement activities. Most importantly, today's rule provides the appropriate regulatory authority with adequate means to discover, evaluate, and, if necessary, terminate an exemption (for example, determine that the claim is inappropriate because the claimant failed to correct the problem). The appropriate regulatory authority can terminate the reclaimed exemption at any time for violations and does not need a waiting period to do so. Therefore, the final rule does not require a waiting period before you can reclaim an exemption for your waste. However, we want to ensure that the appropriate regulatory authority is aware that you have lost the conditional exemption for your waste before you reclaim the exemption. Therefore, you may not reclaim the exemption for your waste until after you have received a return receipt confirming that the Director has received your notification of loss of exemption. This requirement will allow the appropriate regulatory authority to initiate action, if necessary, while minimizing your burden.

G. How Did We Conduct Our Technical Assessment for the Disposal of Treated Waste at Low-Level Radioactive Waste Disposal Facilities?

We conducted a technical assessment to evaluate the protectiveness afforded by a combination of the conditions of the exemption and NRC criteria for the LLRWDF. We considered a number of factors in the analysis:

- LDR treatment and waste container conditions;
- NRC waste form requirement;
- NRC/EPA disposal site properties comparison;
- Disposal unit engineering design and performance;
- NRC groundwater monitoring;
- Other NRC/EPA regulatory comparisons.

We made our technical determination on the comparability between the NRC and EPA disposal systems based on the consideration of all of the above factors. This determination is not based solely on any one factor, but on the aggregation of all the factors considered.

In our technical assessment, we considered these factors and the potential for release of chemical constituents from LLMW disposed of in LLRWDFs, and concluded that the threat of such a release would not be significant. Several significant factors that helped support this conclusion are briefly summarized below. More detail on these factors, and a discussion of other factors that we considered, is provided in the proposed rule preamble

and the technical background document. (See Technical Evaluation, Ref. 7.)

We assessed the likelihood of a chemical release from the disposal of waste in a LLRWDF under the conditions of this rulemaking. The intent of RCRA LDR treatment standards is to significantly reduce the toxicity and mobility of chemical constituents. We performed a screening risk analysis to assess the potential for leachate releases of these constituents from wastes treated to LDR levels. We concluded that the potential threat to drinking water would be insignificant. In addition, prior to disposal the treated waste must be containerized. Therefore, we concluded, based on the treatment to LDR for both RCRA and as a condition of this rule, and container conditions along with the LLRWDF cap design performance comparable to RCRA Subtitle C performance, the potential threat to drinking water would be very low, if any.

We also assessed the protection afforded by NRC waste form criteria. NRC waste form criteria for low level waste stipulates that the waste be stabilized to ensure the structural integrity of the waste for the duration when the radioactive waste is undergoing decay. The requirement for waste form is to minimize the potential for waste/liquid contact and subsequent leachate production. Depending on the radioactivity of the waste, the structural integrity of the waste is required to last up to 500 years. The waste must pass a series of American Society of Testing Methods (ASTM) tests to demonstrate its compliance with the waste form criteria. These tests provide indication of waste form performance in the area of, among other things, structural integrity and resistance to corrosion.

We evaluated NRC's LLRWDF siting requirements and compared them to RCRA hazardous waste disposal facility siting requirements. We found that the siting requirements are very similar, with NRC siting requirements being more stringent in certain respects. The NRC siting requirement for LLRWDFs are designed to enhance the protectiveness of the disposal unit and minimize releases to the environment. These regulations ban location of disposal facilities in environmentally sensitive locations such as, 100-year flood plains, wetlands, and coastal high hazard areas. These requirements also mandate restrictions for ground water to surface water connectivity on-site.

We assessed NRC LLRWDF engineering design and performance requirements and concluded they will effectively minimize water infiltration and waste migration from the disposal cell. The LLRWDFs must be designed to limit human exposure to a specified level of radioactivity and intrusion by humans and animals. NRC LLRWDF disposal regulations require that the engineered landfill design system integrate both the site properties (climate, soil geology) along with the performance of the cover system. LLRWDFs must be designed to provide assurance that concentrations of radioactive material that may be released to ground water, surface water, air, soil, plants, or animals not result in exposures to humans above specified health-based levels. NRC and EPA disposal regulations require a final cover with low permeability to minimize infiltration of precipitation and contact of waste with infiltrated water. NRC LLRWDF disposal regulations also require a landfill design that promotes short liquid/waste residence time which would minimize the potential leachate generation at LLRWDFs.

NRC's ground water monitoring regulations require that groundwater be monitored to allow for early detection and mitigation of radiological contamination. In practice, the NRC Agreement States have also included requirements in the LLRWDFs license to monitor for selected chemical constituents.

We also estimated the annual amount of mixed waste that is expected to be disposed of at LLRWDFs under this conditional exemption. Commercial sources of mixed waste would constitute less than 0.5% of the annual total waste volume at these sites. This amount of disposal volume is expected to contribute very limited volumes of hazardous waste.

In addition to the major technical factors outlined above, we also analyzed other aspects of the NRC regulatory and licensing program for LLRWDFs. This analysis is described in detail in the technical background document. (See Technical Evaluation, Ref. 7.) Some of the key findings include:

- The NRC licensing process provides for public participation and scrutiny of potential disposal facilities, which plays an important role in not only the siting of a facility but also in prescribing conditions governing its final operation.
- NRC prohibits disposal of waste with free liquids greater than 1% by volume, waste contaminated with reactive, explosive, volatile, and corrosive materials, and LLW that is incompatible with containers used for disposal of LLW.
- NRC regulations require active care disposal facility surveillance for up to 100 years under governmental control and government ownership.
- NRC's LLRWDF disposal regulations require corrective measures for the disposal of radioactive waste to assure that corrective measures are taken if a radiation hazard becomes a groundwater concern.

We received 15 comments pertaining to our overall technical analysis and conclusions. The eleven comments supporting the technical approach came from industry associations, generators, academia, and some government agencies. They felt that the approach was thorough and presented compelling analysis supporting the conditional exemption. They agreed that the combination of LDR treatment in conjunction with the stringent controls already in place at the LLRWDFs were protective of human health and the environment. Some commenters argued that dual regulation is not appropriate and only seems to hinder the timely disposal of waste. Based on our analysis that disposal of LLMW would be properly managed in a LLRWDF, without degradation to human health and the environment, the redundant regulation by RCRA adding additional cost and time to permit the facility does not seem prudent.

In contrast, we also received four negative reactions to the technical approach from environmental groups and some State agencies. Some of the comments related to the uncertainties inherent in the analysis. Another commenter believed that we need to address all contingencies and technical aspects before making our final decision. Although there are always uncertainties associated with complex environmental analysis, we are confident of the conclusions of our technical analysis that indicate the RCRA exemption conditions coupled with the NRC performance requirements will be protective of human health and the environment. Our comfort derives from having designed a waste management scheme with multiple redundant systems and conditions that will limit contaminant movement. These include waste treatment, waster form, containers, cover performance, monitoring, and site-specific public participation. We believe that we have addressed all major technical aspects and waste management contingencies in making our decision on the comparability of the two regulatory programs.

Our responses to major comments on specific technical issues are presented in the following sections.

1. Synergistic Effects

Commenters indicated that the radioactive portion of the waste could negatively influence the nature and mobility of the hazardous portion of the waste and similarly the hazardous portion could possibly enhance the mobility of the radioactive constituents. Commenters also raised concerns regarding potential toxicological interaction between the hazardous and radioactive fractions in mixed waste. Interaction between radioactive and hazardous waste components that enhance the mobility or toxicity of constituents is referred to as ''synergy.'' The agency acknowledges that interaction between the waste components may be possible. There is not an adequate scientific understanding of such processes (e.g., synergy and cumulative interactions) that would allow EPA to design additional, and appropriate, management standards, if needed. In addition, the current regulatory schemes do not explicitly account for such effects. Our redundant control systems would make the possibility of such effects remote and go beyond current management practices. From a practical perspective, we concluded that the synergistic effects between radioactive and hazardous constituents would be minimal due to treatment requirements minimizing the hazardous constituents, waste form requirements, container conditions of the waste minimizing radioactive and hazardous interaction, and cover requirements resulting in the lack of liquid to generate leachate. Indeed, the container condition will enhance protectiveness over the current scheme, under which LLMW could interact more readily in a landfill with other radioactive or hazardous wastes.

2. Groundwater Monitoring

Today's final rule does not require LLRWDFs that accept LLMW under the provisions of today's transportation and disposal exemption to conduct groundwater monitoring for chemical constituents. These facilities already are required to conduct groundwater monitoring for radioactive material and other indicators which include selected hazardous constituents. We believe that this monitoring will provide adequate warning if there is a breach of the containment systems at the disposal facility.

A significant number of commenters agreed with the Agency's approach to not require groundwater monitoring for the RCRA constituents as one of the conditions of the disposal exemption because they believed the current NRC and Agreement provisions adequately address the monitoring needs for disposal sites. One commenter pointed out that the Agreement States have the authority to require groundwater monitoring for non-radiological constituents in the license for hazardous constituents under NRC regulations. This commenter noted that additional monitoring (if needed) can be best established as part of the site license condition with the Agreement State and be tailored to the local environmental conditions and the nature of the waste being accepted for disposal. EPA's analysis supports this contention. All three existing LLRWDFs licensed by the Agreement States have groundwater monitoring for RCRA hazardous constituents in their licenses. We believe this data will supplement the groundwater monitoring data of the radioactive constituents in providing the necessary warning sign when there may be a breach of containment at the disposal facility. Further, we found no evidence to suggest that these facilities have ground water contamination above regulatory levels for hazardous constituents as a result of disposal unit design problems or management.

In the proposed rule we specifically asked if commenters knew of reasons why we should include groundwater monitoring requirements for RCRA hazardous constituents as part of the conditional exemption. Some commenters believed that we had not adequately supported our assumption that controlling radionuclides will also adequately control hazardous constituents, because hazardous constituents may be more mobile than radionuclides. One commenter added that monitoring requirements should be based on the contents of the disposal cells; that is, if there are hazardous constituents in the disposal cell, they should be included on the list of analytes to be monitored.

The concerns expressed by these comments are addressed first and foremost by the preconditions established in today's rule for the exempted wastes. Specifically, the LLMW will be treated. Organics will be destroyed and metals will be immobilized through meeting the LDR standards. There will be no free liquid. The waste will then be containerized, at a minimum in carbon steel drums, prior to being placed in the disposal environment. Stable Class-A waste that is mixed with more active Class-B or C waste will meet the NRC requirement of high integrity containers (HICs) (e.g., concrete casks). This system of controls should preclude both transport alluded to by the commenter (e.g., organic solvents either moving faster than other constituents or promoting transport of inorganic constituents) and uncontrolled leaching of inorganic constituents (e.g., the inorganic constituents will be immobilized and unavailable for leaching, if not already destroyed by thermal treatment, and will be contained).

Although we believe the likelihood of hazardous constituent releases is minimal for the reasons presented above, we still believe that ground water monitoring is a prudent safeguard. The NRC/Agreement States already require LLRWDFs to conduct groundwater monitoring for radionuclides and other indicators (including selected hazardous constituents) using traditional analytical methods. The NRC/Agreement States ensure that the monitoring protocols established by the LLRWDFs are based on the wastes and constituents disposed of in the facility. Therefore, the list of analytes will include indicator constituents that are representative of the materials in the facility. In general, the migration of metals, whether as hazardous constituents or radioactive, will migrate in a similar way. We note that the detection of an indicator radioisotope (e.g., Cr-51, Cu-64, Pb-201, Se-75, Tl-201, or Zn-63) would also serve as an indicator of migration of the chemical portion of the waste. For example, if mixed waste contains hazardous chromium and radioactive CR–51 and groundwater monitoring detects CR–51, it would be reasonable to expect that hazardous chromium is also present in groundwater. As noted above, the three operating LLRWDFs monitor for RCRA constituents, including metals and some of the more mobile organic constituents (e.g., benzene, xylene). In conclusion, we are satisfied that the NRC ground water monitoring program will provide adequate protections for the exempted wastes managed under today's rule.

3. Site-Specific Variance

The Agency solicited comment on the use of a ''site-specific, risk-based variance'' approach to determine the waste disposal eligibility. We proposed this alternative to the conditional exemption based on States' interest to factor in site properties into the risk determination. In addition to the site-specific approach, the Agency also solicited comment on the need for guidance in support of performing site-specific risk assessments. Today's final rule regarding the ''conditional exemption'' for disposal does not include the site-specific, risk-based variance approach as an alternative method for exemption. The

requirements identified in the final rule and the existing NRC and Agreement State regulations, guidance, and licences were deemed to be adequate and protective for the management of these wastes.

We received more than forty comments on the use of site-specific, risk-based variances for the determination of waste disposal acceptability. The comments represented a wide disparity of positions. Many comments from States supported the use of the site-specific risk-based alternative to the conditional exemption. The commenters expressed the concern that efforts outside of site-specific modeling would not properly reflect the conditions at a specific site, either by overestimating or underestimating disposal performance. The commenters argued that using a national approach would tend to average site conditions and not truly represent any specific site resulting in uncertainty around the conclusion regarding the qualifications of natural and engineered site conditions.

A set of industry comments did not support the use of site-specific, risk-based analysis, in lieu of the conditional exemption. Their position was that the conditional exemption was technically sound and was instantly available, whereas the site-specific alternative would take time to perform and delay decisionmaking.

One environmental commenter opposed the use of site-specific, risk-based analysis completely on the grounds that the state of the science was not appropriate and too much uncertainty surrounded this type of analysis.

We have decided not to include the site-specific, risk-based alternative in the final rule. We concluded that the disposal of LLMW in LLRWDFs would be protective and be properly managed based on the benefits derived from siting, LDR treatment and waste form requirements, and the protection afforded by LLRWDFs licensed pursuant to 10 CFR part 61. Our review of NRC regulations, guidance, and licenses indicated that disposal facilities provide adequate protection for the disposal of LLMW so long as the additional conditions and requirements of this rule are met. In summary, the approach adopted in this rule will ensure that any potential risks that arise as a consequence of site-specific circumstances will be thoroughly reviewed and mitigated through the NRC licensing process.

H. Why Is Financial Assurance Beyond 10 CFR Part 61 Not Necessary?

You are not required to provide additional financial assurance beyond what NRC requires under 10 CFR part 61 or an NRC Agreement State requires under the state equivalent regulations. This decision is based on our review and comparison of EPA and NRC financial assurance regulations. (See comparison document, Ref. 18.) Both EPA and NRC financial assurance regulations require a disposal facility to provide sufficient funding to enable a third-party to conduct closure and post-closure care activities. Financial assurance for closure and post-closure activities are the key elements of financial assurance requirements under both EPA and NRC regulations. Based on our comparison and analysis of EPA and NRC financial assurance regulations, we have determined that the financial assurance provided by the NRC regulations will ensure that sufficient funds will be available to conduct the similar closure and post-closure care activities at a LLRWDF as required under RCRA. We note that there are variations between EPA and NRC financial assurance requirements. However, we conclude that as a whole, the NRC financial assurance requirements for the LLRWDF are adequately protective, making additional EPA financial assurance requirements for a LLRWDF unnecessary.

Similar to the financial assurance requirements set out under 40 CFR part 264 subpart H for a RCRA hazardous waste disposal facility, 10 CFR part 61 requires a LLRWDF to establish financial assurance that will provide funding for activities such as decommissioning and closure of the facility, cover placement over the disposal unit, post-closure care, and monitoring. NRC and NRC Agreement States do not issue licenses to facilities that cannot obtain financial assurance and these regulatory authorities will revoke licenses from facilities that cannot maintain adequate coverage.

For post-closure care, the NRC and NRC Agreement States require the LLRWDFs to provide financial assurance for an initial monitoring period of five years (or longer if deemed necessary by the regulatory authority) followed by a period of institutional control. At the completion of the five-year (or longer) initial post-closure monitoring period, the license of the LLRWDF is transferred from the disposal facility operator to the State or other Federal Agency who is the property owner. At that time, the next phase of the post-closure care period begins. This second phase of the post-closure care period is the institutional control period. The activities conducted under the institutional control period include monitoring, maintenance of cover, and access control. The NRC or NRC Agreement States also require that the LLRWDF licensees' financial assurance include all the costs associated with the institutional control phase of the post-closure care period. Specifically, prior to the issuance of the license, the applicant needs to provide for NRC review and approval, a copy of a binding arrangement between the applicant and the disposal site owner that ensures that sufficient funds will be available to cover the costs of monitoring and any required maintenance during the institutional control period. (See 10 CFR part 61.) The NRC or NRC Agreement State reviews this arrangement periodically to ensure that changes in inflation, technology, and disposal facility operations are reflected in the arrangements. Thus, the responsibility for funding the institutional control period belongs to the licensee and is assured prior to the issuance of the license and subsequent transfer of the license to the State or Federal Agency for institutional control of the LLRWDF. The institutional control period may last up to 100 years thus providing financial assurance for a considerably long period of time. In comparison, EPA requires RCRA land disposal facilities to provide for 30 years of post-closure monitoring unless the permitting authority modifies the monitoring period.

Although we determined that the EPA and NRC financial assurance requirements are not identical under a requirement-by-requirement comparison, we believe that the overall NRC financial assurance requirements are adequately protective of human health and the environment for a LLRWDF receiving the exempted waste. However, we requested public comment on whether we should require LLRWDFs to provide additional RCRA financial assurance as part of the conditional exemption.

Some commenters supported our proposal of not imposing the RCRA financial assurance requirement for LLRWDFs, because they believed adequate financial assurance exists under NRC regulations. Some of these commenters noted that further financial assurance requirements could discourage LLRWDFs from accepting the exempted wastes. Other commenters believed that it is necessary to impose the additional RCRA financial assurance requirement on a disposal facility

receiving the exempted waste to address the chemical constituents that will be disposed of there.

As discussed above, our analysis showed that the NRC or NRC Agreement State provisions for financial assurance will ensure that sufficient funds will be available to conduct closure and post-closure care activities which are the key elements of RCRA financial assurance requirements. We do not expect the cost for closure activities such as cover placement and post-closure maintenance activities, at a LLRWDF receiving the exempted waste to differ from the cost for the same activities at the same LLRWDF if it did not receive the exempted waste. Because NRC regulations already require financial assurance for closure and post-closure activities, additional funding requirements for the same activities would be redundant.

We also believe that the NRC financial assurance requirement for decommissioning activities is adequate for a LLRWDF that accepted the exempted waste. We note that NRC guidance has a provision that requires cost estimates for decommissioning to include the management of mixed waste (which includes the RCRA chemical constituents) during the decommissioning process. (See ''NMSS Decommissioning Standard Review Plan [NUREG/SR–1727]''.) Therefore, we believe that the NRC financial assurance requirement is adequate, and we do not need to require additional RCRA financial assurance requirements.

IX. Regulatory Impacts

We anticipate that implementation of this rule will result in positive net benefits, resulting from cost savings and risk reductions. We have based our assessment on the best data available; full references and details are available in the Regulatory Impact Analysis which accompanies today's rule. (See Ref. 14.)

The primary benefit of this rule is in facilitating treatment and disposal of mixed wastes, by addressing problems caused by dual regulation of these wastes. We estimate quantified net benefits of this rule to range between $4.1 million and $5.9 million per year. Sections A and B below provide further detail on benefits and costs associated with this rule; Section C addresses economic impacts. We base assessment of benefits and costs on a comparison of waste management after implementation of this final rule compared with waste management in the absence of this rule.

Significant uncertainties make it unusually difficult to estimate the impacts of this rulemaking. In addition to uncertainties about the quantities of LLMW generated in the U.S. there are also questions about the eventual disposition of these wastes. Although this rulemaking creates opportunities for disposal of much of this waste, these opportunities also depend on as-yet undetermined action by State regulatory agencies, low-level radioactive waste disposal facilities, and the generators themselves. These uncertainties and assumptions, however, do not affect the Agency's projection of positive net benefits stemming from this rule; they only affect the magnitude of that net benefit. To the extent that any generators can take advantage of storage or disposal provisions of this proposal, net benefits will accrue.

A. What Are the Regulatory Benefits of This Rule?

The storage component of the rule provides the most significant benefits of this rule, from administrative cost savings and from allowing certain mixed wastes to decay-in-storage. Dollar savings from the disposal portion of this rulemaking are likely to be low, even more so if the LLRWDFs (especially Envirocare) do not accept the exempted waste for disposal as LLRW. To estimate the impact of the rule, EPA first needed to characterize generation and management of low-level waste and low-level mixed waste in the nation.

In 1990, EPA, NRC and the Oak Ridge National Laboratory conducted a survey of commercially generated low-level mixed waste. A report of the survey findings was published in 1992 under the title National Profile on Commercially Generated Low-Level Radioactive Mixed Waste. (See Ref. 8.) As stated in the Executive Summary, ''The * * * objective of the work was to compile a national profile on the volumes, characteristics, and treatability of commercially generated low-level mixed waste * * * by major facility categories * * * [including] academic, industrial, medical, and * * * government facilities and nuclear utilities.''

''The industrial category was estimated to be the largest generator and accumulator of mixed waste, with more than 36% of the generation * * * of the total mixed waste in the United States in 1990.'' (Ref. 8, National Profile, p. 40). Nuclear utilities accounted for roughly 10 percent of the total commercially generated LLMW volume in the United States.

Based on our discussions with the regulated community, we understand that commercial generators of LLMW have taken a number of steps, including pollution prevention, waste minimization, and source reduction (such as using water-based scintillation cocktails as opposed to the solvent-based formulations), to reduce quantities of LLMW they generate. Also, nuclear power plants have instituted steps for controlling the use of organic solvents (for example, establishing procedures to track quantities of organic solvents purchased, used, and left over and discarded). Therefore, despite industrial growth over the intervening years, we believe that the LLMW volumes generated today may be similar to those reported in 1992.

Based on this research and site visits in 1998, we believe that there are a number of LLMW generators, who could benefit from this rulemaking. Using the National Profile we estimated that the national generation rate of mixed waste was 108,000 cubic feet per year. (See Regulatory Impact Analysis, Ref. 14, and Regulatory Impact Analysis, Background Documents, Ref. 17.) Some federal facilities also generate LLMW. The total volume of LLMW generated annually by DOE facilities far exceeds the volume generated by the commercial sector.

Benefits from this rule may accrue in the following areas.

- Permitting cost savings. Those generators needing RCRA permits only for storage or treatment of their mixed wastes will save these permitting costs and associated corrective action costs. These cost savings are approximated at $2.7 million per year.
- Other administrative cost savings. Generators of mixed waste and Federal and State RCRA regulating agencies are expected to save approximately $700,000 in administrative burden and costs because of this rule.
- Decay-in-storage cost savings. The rule will allow facilities to store certain wastes while the radioactivity decays. These wastes can then be treated and disposed of as hazardous waste, which is less expensive than LLMW treatment and disposal. EPA estimates aggregate cost savings from these waste streams will be between $800,000 and $2.6 million per year.
- Other disposal cost savings. This rule will facilitate disposal of wastes in LLRWDFs, depending on approval by state regulatory agencies and the willingness of LLRWDFs to accept the wastes, as well as limitations of the low-level waste disposal compact system. These limitations mean that the savings from the disposal exemption are expected to be at most $100,000 per year. EPA has not estimated savings resulting from reduced storage costs.
- Risk Reductions. EPA anticipates that generators will take advantage of

this rule to allow certain LLMW to undergo decay-in-storage. NRC or the NRC Agreement State approves a decay-in-storage process which allows certain short-lived radionuclides in these wastes to decay to background levels. The remaining decayed waste no longer meets the definition of radioactive under the AEA. Since EPA does not expect these wastes to be treated or handled during the radioactive decay process, waste handlers in treatment and transportation will not be exposed to this radioactivity. Generators who comply with existing RCRA regulations are handling this waste while still radioactive. This decrease in exposure translates to an unquantified risk reduction, attributable to the relaxed RCRA storage restrictions in this rule.

DOE may also save on transportation and disposal costs, to the extent that it chooses to meet the conditions for exemption and dispose of wastes in commercial disposal facilities licensed by NRC or an NRC Agreement State. DOE would not gain permitting or storage cost savings, since the storage and treatment conditional exemption regulations in this rule do not apply to DOE facilities.

B. What Are the Costs of This Rule?

Generators taking advantage of storage or disposal exemptions will incur costs to meet notification conditions. EPA estimates these costs to be approximately $200,000 per year, in the aggregate.

Under this rule, there will also be some increased costs to EPA and RCRA authorized States overseeing management of mixed wastes. We expect these entities to incur costs associated with notification conditions for generators and treaters of exempted LLMW sending their waste for disposal at LLRWDFs and related implementation costs. This will result in a small increase in costs for these regulating bureaus estimated at $5,000 per year, in the aggregate.

C. What Are the Economic Impacts of This Rule?

Economic impacts of this rulemaking are expected to be minimal. Generators who are not meeting regulatory requirements for disposal will incur spending for treatment and disposal of wastes that previously had been stranded in storage. These costs are expected to total about $300,000 in aggregate across the nation. These are not true social costs, though, since these generators are already liable for costs of treatment and disposal of these wastes. The effect of this rule will be to open up disposal capacity for these wastes which currently do not meet the waste acceptance criteria of the existing LLMW disposal facility. Without this rulemaking, these legacy wastes might simply continue to be stored on-site indefinitely, leaving the generators in violation of RCRA requirements. These generators would incur not only storage costs, but social costs associated with being in violation of RCRA.

By allowing LLMW to be disposed of as LLW, this rule may have impacts on the national market for disposal of LLW, although we have not specifically modeled these impacts. The larger the volume to be added to the disposal market, the greater the effects are likely to be. The largest volumes of LLW potentially to be disposed of at commercial LLRWDFs are those generated by the Department of Energy, including wastes from site cleanup and remediation activities. Wastes from commercial LLMW alone are not likely to have any significant impact on these markets.

The only possible negative impact may fall upon the single mixed waste disposal facility which currently accepts some LLMW for disposal. By allowing LLRWDFs to dispose of the LLMW that meets Land Disposal Restrictions, this rule may introduce some competition into the market for disposal of LLMW.

X. State Authorization

As of December 2000, a total of 43 states and one territory were authorized to implement RCRA mixed waste regulations of 1986 (51 FR 24504), which provide for the hazardous components of mixed waste to be managed under RCRA Subtitle C.[1] Today's rule will apply to the hazardous component of mixed waste in a State that has mixed waste authorization, but only when the State amends its State law and becomes authorized to implement this final rule containing a new conditional exemption. The effective date will be the date the State is authorized for this final rule. This rulemaking affects the RCRA base program implementing the Resource Conservation and Recovery Act of 1976. Therefore, authorization for this rule is not automatic, but depends upon State action. In addition, since the flexibility provided by a conditional exemption for disposal and permitting is considered less stringent than the current RCRA program, States are not required to adopt this final rule. When choosing to adopt this rule, States have the option of being more stringent than a federal requirement where they deem it appropriate. (See 40 CFR 271.1(i).)

In Alaska, Hawaii, Iowa, Puerto Rico, and the Virgin Islands, which are jurisdictions not authorized to implement any part of the RCRA program, the federal government implements the RCRA program. In these jurisdictions, this final rule will become effective 180 days after the date of publication of this rule.

We encourage States and territories to adopt this conditional exemption. The conditional exemption does not preclude regulation or enforcement by States against generators who are not eligible for the exemption or who do not meet the conditions or requirements of the exemption. Under this regulatory framework, States retain their regulatory oversight and RCRA enforceability provisions over a noncompliant claimant. The flexibility provided by this rule is conditional. A LLMW generator must meet the eligibility provisions and conditions to qualify for and maintain the exemption from hazardous waste storage and disposal regulations. Failure to meet the conditions results in automatic loss of the exemption; failure to meet the requirements may result in fines and penalties under the RCRA hazardous waste enforcement program. In addition, since the transportation and disposal exemption may involve interstate transportation of conditionally exempt waste, the exemption must be authorized in both the State of the generator and the State where the disposal site is located.

Note: If the waste is transported through a State which considers the waste to be hazardous, the transporter must be in compliance with 40 CFR part 263, including manifest provisions. EPA recommends that the initiating facility note that the waste is subject to today's exemption in block 15 of the manifest.

XI. Relationship With Other RCRA and Environmental Programs

A. What Is the Relationship of Today's Rule With Other RCRA Regulatory Programs?

1. Does This Rule Change How You Determine if a Waste Is Hazardous?

No, the hazardous waste determination remains unchanged. This rule is a conditional exemption from the RCRA regulatory definition of hazardous waste. Under current RCRA regulations, if you generate a solid waste, you must determine if it is a

[1] The District of Columbia, Massachusetts, Maryland, Rhode Island and West Virginia are RCRA authorized States that have adopted mixed waste regulations under State law but have not yet been authorized to implement the mixed waste regulations. This rule will become effective in these jurisdictions when the State adopts and is authorized for the final rule.

hazardous waste as outlined in 40 CFR 262.11, Hazardous Waste Determination. A generator of LLMW must also determine if the waste is excluded from regulation under 40 CFR 261.4, Exclusions. Next, a generator must determine whether the waste meets the regulatory description for a listed hazardous waste in subpart D of part 261, Lists of Hazardous Wastes. If the waste is not a listed hazardous waste, the generator must then determine if the waste exhibits a characteristic defined in subpart C of part 261.

2. Can LLMW or Eligible NARM Be a Non-Hazardous Waste Under This Rule?

LLMW, or Eligible NARM, meeting the eligibility criteria and all the conditions under the storage and treatment or transportation and disposal conditional exemption, will be conditionally exempt from the regulatory definition of hazardous waste under RCRA Subtitle C, and therefore managed as non-hazardous waste under this rule.

3. How does the LLMW conditional exemption differ from delisting under 40 CFR 260.22?

The evaluation criteria used for delisting differ from today's rule. In the conditional exemption, the evaluation criteria are national and categorical. This contrasts with the evaluation criteria for delisting, which are based upon a designated waste stream and are case specific. In delisting, we evaluate the processes generating a specific waste stream to determine the constituents likely to be present, as well as the potential variability in the waste. In addition, conditionally exempt LLMW must be managed in accordance with applicable NRC regulations. Delisted waste is generally managed as an industrial solid waste.

4. Will My Waste Analysis Plan of My RCRA-Permitted TSDF Change?

No, your waste analysis plan will not change. If you are a generator or an owner or an operator of a RCRA-permitted or interim status TSDF, also licensed by the NRC for managing LLW, and plan to claim a conditional exemption, you remain subject to the waste analysis and waste analysis plan requirements of 40 CFR part 268. If you treat to Land Disposal Restriction standards, you must have a waste analysis plan. This includes DOE treatment facilities treating LLMW to meet the conditions for the disposal exemption.

5. Will the Final Rule Change How the RCRA Closure Requirements Apply to My Disposal Facility?

If you have a disposal facility subject to NRC or NRC Agreement State regulations for disposal of LLW, and you accept conditionally exempt waste under this rule, the hazardous waste facility closure requirements do not apply to any units at your facility receiving only conditionally exempt LLMW.

6. How Does the Conditional Exemption Relate to RCRA Air Emission Standards?

RCRA Air Emission Standards do not apply to a LLRWDF where conditionally exempt LLMW or Eligible NARM waste has been disposed of.

B. What Is the Relationship of This Rule to Other Environmental Programs?

1. How Are CERCLA Actions Affected by Today's Rule?

The affect of today's rule on Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) actions depends on whether the waste will be managed on or off the CERCLA site. Off-site disposal of CERCLA remediation waste must comply with all conditions of today's final rule for a generator to take advantage of the exemption provided, including that the waste must be disposed of at a LLRWDF that is licensed by the NRC or an NRC Agreement State, and is in compliance with the 10 CFR part 61 or equivalent State regulations. Off-site rule requirements in 40 CFR part 300 continue to apply to CERCLA remediation wastes.

Mixed waste managed during on-site waste remediation must meet all applicable or relevant and appropriate requirements of Federal or State environmental laws or justify a waiver from those standards. This rule requires that the disposal facility be licensed and overseen by the NRC or NRC Agreement State. On-site CERCLA response action must comply with the substantive provisions of environmental regulations and standards, but not the administrative provisions. Therefore, no permit or license is required for on-site activities. In accordance with the National Contingency Plan and CERCLA, today's regulation is not expected to be an applicable requirement at most CERCLA sites managing LLMW. However, relevant and appropriate determinations are site-specific and these may or may not be deemed relevant and appropriate given site-specific conditions. In general, we expect that most CERCLA sites will meet both the substantive provisions of the RCRA Subtitle C landfill requirements as well as the 10 CFR part 61 requirements for a LLRWDF.

2. How Might Clean Air Act Regulations Be Affected?

This rule will not affect Clean Air Act regulations. LDR treatment of LLMW or Eligible NARM remains subject to the air emission standards applicable to hazardous waste treatments under RCRA.

3. How Might Clean Water Act Regulations Be Affected?

This rule will not affect Clean Water Act regulations.

XII. Effective Date November 13, 2001

XIII. Regulatory Assessment Requirements

A. Executive Order 12866: Determination of Significance

Under Executive Order (E.O.) 12866, (58 FR 51,735 October 4, 1993) EPA must determine whether the regulatory action is ''significant,'' and therefore, subject to OMB review and the requirements of the Executive Order The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order

Under the terms of Executive Order 12866, it has been determined that this rule is a ''significant regulatory action'' because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order This rule addresses problems caused by dual regulation of mixed wastes, and facilitates treatment and disposal of mixed wastes. We estimate quantified net benefits of this rule to range between $4.1 million and $5.9 million per year. As a significant regulatory action this rule was submitted to OMB for review. Changes made in response to OMB

suggestions or recommendations will be documented in the public record.

Under the terms of Executive Order 12866, EPA must prepare for any significant regulatory action an assessment of the action's potential costs and benefits. If that action satisfies the first of the criteria listed above, this assessment must include, to the extent feasible, a quantification of these costs and benefits, the underlying analyses supporting such quantification, and an assessment of the costs and benefits of reasonably feasible alternatives to the planned regulation. This final rule is not economically significant, although it is expected to yield net benefits to society because of reduced waste management and administrative costs for both generators of mixed waste and regulatory agencies, and reduced worker exposures. A summary description of costs and benefits associated with this final rule appears in section IX of this preamble. A regulatory impact analysis has been prepared and is available in the docket for today's final rulemaking.

B. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132, because the rule will not impose any requirements on States or any other level of government. As explained above, today's final rule may provide regulatory flexibility for generators and treaters of LLMW by establishing a conditional exemption from RCRA Subtitle C requirements, which States are not required to adopt. Thus, the requirements of the Executive Order do not apply to this rule.

C. Executive Order 12898: Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations' as well as through EPA's April 1995, ''Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report'' and National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population—regardless of race, color, national origin, or income—bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities.

To address this goal, EPA considered the impacts of this rule on low-income populations and minority populations. This waste would be stored according to other regulatory authorities (NRC or NRC Agreement States) which offer comparable protection to RCRA Subtitle C. We evaluated the demographics of the areas surrounding the three existing commercial low-level radioactive waste disposal facilities. We did not find disproportionate populations of minority groups residing in the surrounding area. Most importantly, we do not expect adverse environmental impact as a result of the disposal rule. The RCRA exempted waste will have been treated, for example, to destroy hazardous organic constituents and stabilize toxic metals. The waste would then be placed in a container, managed, and disposed of, in an environmentally sound manner according to NRC or NRC Agreement State equivalent regulations for disposal of low-level radioactive waste. Therefore, we believe there will not be disproportionately high and adverse environmental or economic impacts on any minority or low-income group, or on any community.

D. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997) applies to any rule that is determined to be ''economically significant'' as defined under Executive Order 12866, and concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because the Agency does not have reason to believe the environmental or health and safety risks addressed by this action present a disproportionate risk to children. We find that waste management under NRC regulations for radioactive waste could diminish (not increase) concerns regarding environmental health or safety risks for all, including children.

E. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

On November 6, 2000, the President issued Executive Order 13175 (65 FR 67249) entitled, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 took effect on January 6, 2001, and revoked Executive Order 13084 (Tribal Consultation) as of that date. EPA developed this final rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. This Executive Order requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process that permits elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Prior to the publication of the November 1999 proposal, we briefed two organizations with an interest in tribal environmental issues on both the storage and disposal exemptions we

were proposing. The organizations were the American Indian Environmental Office, and the executive director and staff of the Tribal Association of Solid Waste and Emergency Response (TASWER). TASWER staff indicated that there was an annual tribal conference the following week and the representatives of tribes in attendance would be informed about our proposed rule and encouraged to comment. None of the comments received were identified by the sender as representing tribes. Based on the discussion at our meetings with tribal organizations, we do not expect this rule to significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of Section 3(b) of Executive Order 13084 do not apply to this rule.

F. The Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 et seq.)

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that meets the Small Business Administration size standards established for industries as described in the North American Industry Classification System (see *http://www.sba.gov/size/NAICS-cover-page.html*); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' (5 U.S.C. 603 and 604.) Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

The overall economic effect of this regulation has been determined to be a net savings to all regulated entities that choose to avail themselves of a conditional exemption for storage or disposal of the mixed wastes they generate. This rule will not impose additional costs on any entities. We have therefore concluded that today's final rule will relieve regulatory burden for all small entities.

G. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of sec. 205 do not apply when they are inconsistent with applicable law. Moreover, sec. 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector because it imposes no enforceable duty on any State, local, or tribal governments or the private sector. Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

H. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law No. 104–113 Section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, with explanations when the Agency decides not to use available and applicable voluntary consensus standards. This final rule does not involve technical standards. In 1997, EPA and NRC published in the **Federal Register** joint testing guidance for sampling and testing of mixed waste. Facilities subject to this rule may continue to use that guidance, which allows analysis of smaller samples and reduces exposure of workers to radiation hazards.

I. Paperwork Reduction Act

Under the implementing regulations for the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), an agency is required to certify that any agency-sponsored collection of information from the public is necessary for the proper performance of its functions, has practical utility, does not unnecessarily duplicate information otherwise reasonably accessible to the agency, and reduces to the extent practicable and appropriate the burden on those required to provide the information. (5 CFR 1320.9.) Any proposed collection of information must be submitted, along with this certification, to the Office of Management and Budget (OMB) for approval before the collection of information goes into effect.

The information collection requirements in this final rule have been submitted for approval to OMB under the Paperwork Reduction Act. An

Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1922.01), and a copy may be obtained from Sandy Farmer, Office of Environmental Information, Collection Strategies Division, U.S. Environmental Protection Agency (2137), 1200 Pennsylvania Ave., NW., Washington, DC 20460 or by calling (202) 260–2740.

This information collection is required to provide documentation of conditional exemption from RCRA Subtitle C requirements. The exemptions from RCRA Subtitle C under today's action would require no government approval before being effective. For this final rule, information collection, maintenance, and reporting issues are especially important. Successful implementation of today's rule will depend upon the documentation, certification, and verification provided by the information collection.

The general authority for this rule is 1006, 2002(a), 3001–3009 and 3013 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), and the Hazardous and Solid Waste Amendments of 1984 (HSWA), and the Federal Facility Compliance Act of 1992 (FFCA), 42 U.S.C. 6905, 6912(a), 6921–6929 and 6934. To the extent that this rule imposes any information collection requirements under existing RCRA regulations promulgated in previous rulemakings, those requirements have been approved by OMB under the Paperwork Reduction Act, and have been assigned one of the following OMB control numbers: 2050–0009 (ICR no. 1573, Part B Permit Application, Permit Modifications, and Special Permits); 2050–0120 (ICR 1571, General Facility Hazardous Waste Standards); 2050–0028 (ICR 261, Notification of Hazardous Waste Activity); 2050–0034 (ICR 262, RCRA Hazardous Waste Permit Application and Modification, Part A); 2050–0039 (ICR 801, Requirements for Generators, Transporters, and Waste Management Facilities under the Hazardous Waste Manifest System); 2050–0035 (ICR 820, Hazardous Waste Generator Standards); and 2050–0024 (ICR 976, 1997 Hazardous Waste Report).

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR parts 9 and 48 CFR chapter 15. This rule includes new information collection requirements subject to OMB review under the Paperwork Reduction Act. To be eligible for a conditional exemption for stored low-level mixed waste, facilities must notify EPA or the RCRA Authorized State of their claims for a conditional exemption for their LLMW and storage units. If they do not choose to claim a conditional exemption, generators will have to comply with the existing Subtitle C recordkeeping requirements for the low-level mixed wastes they generate.

This rule also includes notification requirements for generators or treaters of LLMW and Eligible NARM seeking a conditional exemption from the definition of hazardous waste, which would allow disposal of the waste meeting the conditions for exemption in a low-level radioactive waste disposal facility licensed by NRC or an NRC Agreement State. If the generator or treater of LLMW chooses not to claim an exemption, it remains subject to the existing hazardous waste disposal requirements.

Some of the requirements contained in today's final action entail new reporting and recordkeeping requirements for members of the regulated public, if an exemption is claimed. The requirements have practical utility in that they are necessary to ensure that the disposal of conditionally exempted low-level mixed waste is safely managed. If generators choose to avail themselves of the regulatory flexibility discussed in this final rule, they will be subject to the notification and recordkeeping requirements described above. However, such notification and recordkeeping would replace the paperwork burden required for treatment and storage permits for their low-level mixed wastes if they did not claim a conditional exemption. States (but not Tribes) would have additional recordkeeping requirements for receiving a generator's notice to claim a conditional exemption, and for reviewing a generator's notice to reclaim a conditional exemption.

We have prepared a full ICR in support of today's final rule. We estimate the total annual public burden associated with the storage and treatment conditional exemption to average 3.5 hours per respondent. We estimate the reporting burden to average 1.9 hours per respondent annually, including time for reading the regulations, and preparing and submitting notifications. We estimate the recordkeeping burden to average 1.6 hours per respondent annually, including the time for recording the results of inventories and inspections, and maintaining records pertaining to the mixed waste exemption.

The total public burden associated with the transportation and disposal exemption is estimated to average 3.9 hours per respondent. We estimate the reporting burden to average 2.9 hours per respondent annually, including time for reading the regulations, and preparing and submitting notifications. The annual recordkeeping burden is estimated to average 1.0 hours per respondent and includes the time for maintaining records pertaining to the mixed waste exemption.

Burden means the total time, effort, or financial resources expended to generate, maintain, retain, disclose, or provide information to or for a Federal agency. Burden includes the time needed to:

- Review instructions;
- Develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information;
- Adjust the existing methods to comply with any previously applicable instructions and requirements;
- Train personnel to be able to respond to a collection of information;
- Search data sources;
- Complete and review the collection of information; and
- Transmit or otherwise disclose the information.

We received no public comment on the proposed information collection.

J. The Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective November 13, 2001.

XIV. Supporting Documents

1. EPA Consent Decree, HWIR Settlement Agreement, April 11, 1997.
2. EPA Side-bar letter to EEI/USWAG dated April 7, 1997.
3. ''Review of Waste Management Practices and Compliance History at Nuclear Power Plants and Other Entities that Generate Low-Level Mixed Waste.'' April 12, 1999.

4. ''Comparison of the EPA's RCRA Requirements and the NRC's Licensing Requirements for the Treatment (In Tanks and Containers) and Storage of Low-Level Mixed Wastes at Nuclear Facilities'', April 2001.
5. Comment Summary Document—Approach to Reinventing Regulations of Storing Mixed Low-Level Radioactive Waste; Advance Notice of Proposed Rulemaking (ANPRM), September 21,1999.
6. Report to Utility Solid Waste Activities Group and Utility Nuclear Waste Management Group on Comparative Assessment of the Environmental Protection Agency's Regulations for Hazardous Waste Tank Systems (40 CFR part 265, subpart J) and Comparable Nuclear Regulatory Commission Requirements, July 1988.
7. Technical Evaluation on Document for the Disposal of Mixed Waste at Low-Level Radioactive Waste Disposal Facilities, Draft Technical Background Document, July 1999.
8. National Profile on Commercially Generated Low-Level Radioactive Mixed Waste, NUREG/CR–5938, December 1992.
9. Meeting Notes for EPA Meeting with Low-Level Radioactive Waste Disposal Facilities, December 7, 1998.
10. RCRA Hazardous Constituents and Waste Codes Associated with Mixed Waste, December 1997.
11. Joint State/EPA Workshop on Mixed Waste Rulemaking, October 7–9, 1998, Meeting Summary.
12. Comparison of NRC and EPA's Waste Tracking and Related Record Keeping Requirements, July 1999.
13. Technical Alternatives Considered for Evaluating Protectiveness of Low-Level Waste Disposal Facilities, July 21, 1999.
14. Regulatory Impact Analysis: Storage, Treatment, Transportation, and Disposal of Mixed Waste, February 2001.
15. Summary of Public Comments on ''Contingent Management of Mixed Waste'' Submitted in Response to the 1995 HWIR Proposal, July 1999.
16. The Management of Mixed Low-Level Radioactive Waste in the Nuclear Power Industry, NUMARC/NESP–006, Nuclear Management Resources Council, Inc., Washington, D.C., January 1990.
17. Regulatory Impact Analysis: Storage, Treatment, Transportation, and Disposal of Mixed Waste—Supplemental Documents, February 2001.
18. Comparison of Financial Assurance Requirements Under EPA and NRC Regulations, November, 2000.
19. Discussion with DOT on Mixed Waste Transportation on August 1999.
20. Letter from Elizabeth A. Cotsworth, Director, Office of Solid Waste, to J. Dale Givens, State of Louisiana, Department of Environmental Quality, March 27, 1998.

Note that this is a list of supporting documents for both the proposed and final rules. Reference documents numbered 5, 11, 13, and 15 were referred to in the proposed rule but not in the final rule.

List of Subjects in 40 CFR Part 266

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: April 30, 2001.

Christine Todd Whitman,

Administrator.

For the reasons set forth in the preamble 40 CFR part 266 is amended as follows:

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

1. The authority citation for part 266 is revised to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

2. Part 266 is amended by adding subpart N to read as follows:

Subpart N—Conditional Exemption for Low-Level Mixed Waste Storage, Treatment, Transportation and Disposal

Terms

Sec.

Subpart N—Conditional Exemption for Low-Level Mixed Waste Storage and Disposal

Terms

§ 266.210 What definitions apply to this subpart?

This subpart uses the following special definitions:

Agreement State means a state that has entered into an agreement with the NRC under subsection 274b of the Atomic Energy Act of 1954, as amended (68 Stat. 919), to assume responsibility for regulating within its borders byproduct, source, or special nuclear material in quantities not sufficient to form a critical mass.

Certified delivery means certified mail with return receipt requested, or equivalent courier service, or other means, that provides the sender with a receipt confirming delivery.

Director refers to the definition in 40 CFR 270.2.

Eligible Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM) is NARM that is eligible for the Transportation and Disposal Conditional Exemption. It is a

NARM waste that contains RCRA hazardous waste, meets the waste acceptance criteria of, and is allowed by State NARM regulations to be disposed of at a low-level radioactive waste disposal facility (LLRWDF) licensed in accordance with 10 CFR part 61 or NRC Agreement State equivalent regulations.

Exempted waste means a waste that meets the eligibility criteria in 266.225 and meets all of the conditions in § 266.230, or meets the eligibility criteria in 40 CFR 266.310 and complies with all the conditions in § 266.315. Such waste is conditionally exempted from the regulatory definition of hazardous waste described in 40 CFR 261.3.

Hazardous Waste means any material which is defined to be hazardous waste in accordance with 40 CFR 261.3, ''Definition of Hazardous Waste.''

Land Disposal Restriction (LDR) Treatment Standards means treatment standards, under 40 CFR part 268, that a RCRA hazardous waste must meet before it can be disposed of in a RCRA hazardous waste land disposal unit.

License means a license issued by the Nuclear Regulatory Commission, or NRC Agreement State, to users that manage radionuclides regulated by NRC, or NRC Agreement States, under authority of the Atomic Energy Act of 1954, as amended.

Low-Level Mixed Waste (LLMW) is a waste that contains both low-level radioactive waste and RCRA hazardous waste.

Low-Level Radioactive Waste (LLW) is a radioactive waste which contains source, special nuclear, or byproduct material, and which is not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in section 11e.(2) of the Atomic Energy Act. (See also NRC definition of ''waste'' at 10 CFR 61.2)

Mixed Waste means a waste that contains both RCRA hazardous waste and source, special nuclear, or byproduct material subject to the Atomic Energy Act of 1954, as amended.

Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM) means radioactive materials that:

(1) Are naturally occurring and are not source, special nuclear, or byproduct materials (as defined by the AEA) or

(2) Are produced by an accelerator. NARM is regulated by the States under State law, or by DOE (as authorized by the AEA) under DOE orders.

NRC means the U. S. Nuclear Regulatory Commission.

We or us within this subpart, means the Director as defined in 40 CFR 270.2.

You means a generator, treater, or other handler of low-level mixed waste or eligible NARM.

Storage and Treatment Conditional Exemption and Eligibility

§ 266.220 What does a storage and treatment conditional exemption do?

The storage and treatment conditional exemption exempts your low-level mixed waste from the regulatory definition of hazardous waste in 40 CFR 261.3 if your waste meets the eligibility criteria in § 266.225 and you meet the conditions in § 266.230.

§ 266.225 What wastes are eligible for the storage and treatment conditional exemption?

Low-level mixed waste (LLMW), defined in § 266.210, is eligible for this conditional exemption if it is generated and managed by you under a single NRC or NRC Agreement State license. (Mixed waste generated at a facility with a different license number and shipped to your facility for storage or treatment requires a permit and is ineligible for this exemption. In addition, NARM waste is ineligible this exemption.)

§ 266.230 What conditions must you meet for your LLMW to qualify for and maintain a storage and treatment exemption?

(a) For your LLMW to qualify for the exemption you must notify us in writing by certified delivery that you are claiming a conditional exemption for the LLMW stored on your facility. The dated notification must include your name, address, RCRA identification number, NRC or NRC Agreement State license number, the waste code(s) and storage unit(s) for which you are seeking an exemption, and a statement that you meet the conditions of this subpart. Your notification must be signed by your authorized representative who certifies that the information in the notification is true, accurate, and complete. You must notify us of your claim either within 90 days of the effective date of this rule in your State, or within 90 days of when a storage unit is first used to store conditionally exempt LLMW.

(b) To qualify for and maintain an exemption for your LLMW you must:

(1) Store your LLMW waste in tanks or containers in compliance with the requirements of your license that apply to the proper storage of low-level radioactive waste (not including those license requirements that relate solely to recordkeeping);

(2) Store your LLMW in tanks or containers in compliance with chemical compatibility requirements of a tank or container in 40 CFR 264.177, or 264.199 or 40 CFR 265.177, or 265.199;

(3) Certify that facility personnel who manage stored conditionally exempt LLMW are trained in a manner that ensures that the conditionally exempt waste is safely managed and includes training in chemical waste management and hazardous materials incidents response that meets the personnel training standards found in 40 CFR 265.16(a)(3);

(4) Conduct an inventory of your stored conditionally exempt LLMW at least annually and inspect it at least quarterly for compliance with subpart N of this part; and

(5) Maintain an accurate emergency plan and provide it to all local authorities who may have to respond to a fire, explosion, or release of hazardous waste or hazardous constituents. Your plan must describe emergency response arrangements with local authorities; describe evacuation plans; list the names, addresses, and telephone numbers of all facility personnel qualified to work with local authorities as emergency coordinators; and list emergency equipment.

Treatment

§ 266.235 What waste treatment does the storage and treatment conditional exemption allow?

You may treat your low-level mixed waste at your facility within a tank or container in accordance with the terms of your NRC or NRC Agreement State license. Treatment that cannot be done in a tank or container without a RCRA permit (such as incineration) is not allowed under this exemption.

Loss of Conditional Exemption

§ 266.240 How could you lose the conditional exemption for your LLMW and what action must you take?

(a) Your LLMW will automatically lose the storage and treatment conditional exemption if you fail to meet any of the conditions specified in § 266.230. When your LLMW loses the exemption, you must immediately manage that waste which failed the condition as RCRA hazardous waste, and the storage unit storing the LLMW immediately becomes subject to RCRA hazardous waste container and/or tank storage requirements.

(1) If you fail to meet any of the conditions specified in § 266.230 you must report to us and the NRC, or the oversight agency in the NRC Agreement State, in writing by certified delivery within 30 days of learning of the failure. Your report must be signed by your authorized representative certifying that

the information provided is true, accurate, and complete. This report must include:

(i) The specific condition(s) you failed to meet;

(ii) A description of the LLMW (including the waste name, hazardous waste codes and quantity) and storage location at the facility; and

(iii) The date(s) on which you failed to meet the condition(s).

(2) If the failure to meet any of the conditions may endanger human health or the environment, you must also immediately notify us orally within 24 hours and follow up with a written notification within five days. Failures that may endanger human health or the environment include, but are not limited to, discharge of a CERCLA reportable quantity or other leaking or exploding tanks or containers, or detection of radionuclides above background or hazardous constituents in the leachate collection system of a storage area. If the failure may endanger human health or the environment, you must follow the provisions of your emergency plan.

(b) We may terminate your conditional exemption for your LLMW, or require you to meet additional conditions to claim a conditional exemption, for serious or repeated noncompliance with any requirement(s) of subpart N of this part.

§ 266.245 If you lose the storage and treatment conditional exemption for your LLMW, can the exemption be reclaimed?

(a) You may reclaim the storage and treatment exemption for your LLMW if:

(1) You again meet the conditions specified in § 266.230; and

(2) You send us a notice by certified delivery that you are reclaiming the exemption for your LLMW. Your notice must be signed by your authorized representative certifying that the information contained in your notice is true, complete, and accurate. In your notice you must do the following:

(i) Explain the circumstances of each failure.

(ii) Certify that you have corrected each failure that caused you to lose the exemption for your LLMW and that you again meet all the conditions as of the date you specify.

(iii) Describe plans that you have implemented, listing specific steps you have taken, to ensure the conditions will be met in the future.

(iv) Include any other information you want us to consider when we review your notice reclaiming the exemption.

(b) We may terminate a reclaimed conditional exemption if we find that your claim is inappropriate based on factors including, but not limited to, the following: you have failed to correct the problem; you explained the circumstances of the failure unsatisfactorily; or you failed to implement a plan with steps to prevent another failure to meet the conditions of § 266.230. In reviewing a reclaimed conditional exemption under this section, we may add conditions to the exemption to ensure that waste management during storage and treatment of the LLMW will protect human health and the environment.

Recordkeeping

§ 266.250 What records must you keep at your facility and for how long?

(a) In addition to those records required by your NRC or NRC Agreement State license, you must keep records as follows:

(1) Your initial notification records, return receipts, reports to us of failure(s) to meet the exemption conditions, and all records supporting any reclaim of an exemption;

(2) Records of your LLMW annual inventories, and quarterly inspections;

(3) Your certification that facility personnel who manage stored mixed waste are trained in safe management of LLMW including training in chemical waste management and hazardous materials incidents response; and

(4) Your emergency plan as specified in § 266.230(b).

(b) You must maintain records concerning notification, personnel trained, and your emergency plan for as long as you claim this exemption and for three years thereafter, or in accordance with NRC regulations under 10 CFR part 20 (or equivalent NRC Agreement State regulations), whichever is longer. You must maintain records concerning your annual inventory and quarterly inspections for three years after the waste is sent for disposal, or in accordance with NRC regulations under 10 CFR part 20 (or equivalent NRC Agreement State regulations), whichever is longer.

Reentry Into RCRA

§ 266.255 When is your LLMW no longer eligible for the storage and treatment conditional exemption?

(a) When your LLMW has met the requirements of your NRC or NRC Agreement State license for decay-in-storage and can be disposed of as non-radioactive waste, then the conditional exemption for storage no longer applies. On that date your waste is subject to hazardous waste regulation under the relevant sections of 40 CFR parts 260 through 271, and the time period for accumulation of a hazardous waste as specified in 40 CFR 262.34 begins.

(b) When your conditionally exempt LLMW, which has been generated and stored under a single NRC or NRC Agreement State license number, is removed from storage, it is no longer eligible for the storage and treatment exemption. However, your waste may be eligible for the transportation and disposal conditional exemption at § 266.305.

Storage Unit Closure

§ 266.260 Do closure requirements apply to units that stored LLMW prior to the effective date of Subpart N?

Interim status and permitted storage units that have been used to store only LLMW prior to the effective date of subpart N of this part and, after that date, store only LLMW which becomes exempt under this subpart N, are not subject to the closure requirements of 40 CFR parts 264 and 265. Storage units (or portions of units) that have been used to store both LLMW and non-mixed hazardous waste prior to the effective date of subpart N or are used to store both after that date remain subject to closure requirements with respect to the non-mixed hazardous waste.

Transportation and Disposal Conditional Exemption

§ 266.305 What does the transportation and disposal conditional exemption do?

This conditional exemption exempts your waste from the regulatory definition of hazardous waste in 40 CFR 261.3 if your waste meets the eligibility criteria under § 266.310, and you meet the conditions in § 266.315.

Eligibility

§ 266.310 What wastes are eligible for the transportation and disposal conditional exemption?

Eligible waste must be:

(a) A low-level mixed waste (LLMW), as defined in § 266.210, that meets the waste acceptance criteria of a LLRWDF; and/or

(b) An eligible NARM waste, defined in § 266.210.

Conditions

§ 266.315 What are the conditions you must meet for your waste to qualify for and maintain the transportation and disposal conditional exemption?

You must meet the following conditions for your eligible waste to qualify for and maintain the exemption:

(a) The eligible waste must meet or be treated to meet LDR treatment standards as described in § 266.320.

(b) If you are not already subject to NRC, or NRC Agreement State

equivalent manifest and transportation regulations for the shipment of your waste, you must manifest and transport your waste according to NRC regulations as described in § 266.325.

(c) The exempted waste must be in containers when it is disposed of in the LLRWDF as described in § 266.340.

(d) The exempted waste must be disposed of at a designated LLRWDF as described in § 266.335.

§ 266.320 What treatment standards must your eligible waste meet?

Your LLMW or eligible NARM waste must meet Land Disposal Restriction (LDR) treatment standards specified in 40 CFR part 268, subpart D.

§ 266.325 Are you subject to the manifest and transportation condition in § 266.315(b)?

If you are not already subject to NRC, or NRC Agreement State equivalent manifest and transportation regulations for the shipment of your waste, you must meet the manifest requirements under 10 CFR 20.2006 (or NRC Agreement State equivalent regulations), and the transportation requirements under 10 CFR 1.5 (or NRC Agreement State equivalent regulations) to ship the exempted waste.

§ 266.330 When does the transportation and disposal exemption take effect?

The exemption becomes effective once all the following have occurred:

(a) Your eligible waste meets the applicable LDR treatment standards.

(b) You have received return receipts that you have notified us and the LLRWDF as described in § 266.345.

(c) You have completed the packaging and preparation for shipment requirements for your waste according to NRC Packaging and Transportation regulations found under 10 CFR part 71 (or NRC Agreement State equivalent regulations); and you have prepared a manifest for your waste according to NRC manifest regulations found under 10 CFR part 20 (or NRC Agreement State equivalent regulations), and

(d) You have placed your waste on a transportation vehicle destined for a LLRWDF licensed by NRC or an NRC Agreement State.

§ 266.335 Where must your exempted waste be disposed of?

Your exempted waste must be disposed of in a LLRWDF that is regulated and licensed by NRC under 10 CFR part 61 or by an NRC Agreement State under equivalent State regulations, including State NARM licensing regulations for eligible NARM.

§ 266.340 What type of container must be used for disposal of exempted waste?

Your exempted waste must be placed in containers before it is disposed. The container must be:

(a) A carbon steel drum; or

(b) An alternative container with equivalent containment performance in the disposal environment as a carbon steel drum; or

(c) A high integrity container as defined by NRC.

Notification

§ 266.345 Whom must you notify?

(a) You must provide a one time notice to us stating that you are claiming the transportation and disposal conditional exemption prior to the initial shipment of an exempted waste from your facility to a LLRWDF. Your dated written notice must include your facility name, address, phone number, and RCRA ID number, and be sent by certified delivery.

(b) You must notify the LLRWDF receiving your exempted waste by certified delivery before shipment of each exempted waste. You can only ship the exempted waste after you have received the return receipt of your notice to the LLRWDF. This notification must include the following:

(1) A statement that you have claimed the exemption for the waste.

(2) A statement that the eligible waste meets applicable LDR treatment standards.

(3) Your facility's name, address, and RCRA ID number.

(4) The RCRA hazardous waste codes prior to the exemption of the waste streams.

(5) A statement that the exempted waste must be placed in a container according to § 266.340 prior to disposal in order for the waste to remain exempt under the transportation and disposal conditional exemption of subpart N of this part.

(6) The manifest number of the shipment that will contain the exempted waste.

(7) A certification that all the information provided is true, complete, and accurate. The statement must be signed by your authorized representative.

Recordkeeping

§ 266.350 What records must you keep at your facility and for how long?

In addition to those records required by your NRC or NRC Agreement State license, you must keep records as follows:

(a) You must follow the applicable existing recordkeeping requirements under 40 CFR 264.73, 40 CFR 265.73, and 40 CFR 268.7 of this chapter to demonstrate that your waste has met LDR treatment standards prior to your claiming the exemption.

(b) You must keep a copy of all notifications and return receipts required under §§ 266.355, and 266.360 for three years after the exempted waste is sent for disposal.

(c) You must keep a copy of all notifications and return receipts required under § 266.345(a) for three years after the last exempted waste is sent for disposal.

(d) You must keep a copy of the notification and return receipt required under § 266.345(b) for three years after the exempted waste is sent for disposal.

(e) If you are not already subject to NRC, or NRC Agreement State equivalent manifest and transportation regulations for the shipment of your waste, you must also keep all other documents related to tracking the exempted waste as required under 10 CFR 20.2006 or NRC Agreement State equivalent regulations, including applicable NARM requirements, in addition to the records specified in § 266.350(a) through (d).

Loss of Transportation and Disposal Conditional Exemption

§ 266.355 How could you lose the transportation and disposal conditional exemption for your waste and what actions must you take?

(a) Any waste will automatically lose the transportation and disposal exemption if you fail to manage it in accordance with all of the conditions specified in § 266.315.

(1) When you fail to meet any of the conditions specified in § 266.315 for any of your wastes, you must report to us, in writing by certified delivery, within 30 days of learning of the failure. Your report must be signed by your authorized representative certifying that the information provided is true, accurate, and complete. This report must include:

(i) The specific condition(s) that you failed to meet for the waste;

(ii) A description of the waste (including the waste name, hazardous waste codes and quantity) that lost the exemption; and

(iii) The date(s) on which you failed to meet the condition(s) for the waste.

(2) If the failure to meet any of the conditions may endanger human health or the environment, you must also immediately notify us orally within 24 hours and follow up with a written notification within 5 days.

(b) We may terminate your ability to claim a conditional exemption for your

waste, or require you to meet additional conditions to claim a conditional exemption, for serious or repeated noncompliance with any requirement(s) of subpart N of this part.

§ 266.360 If you lose the transportation and disposal conditional exemption for a waste, can the exemption be reclaimed?

(a) You may reclaim the transportation and disposal exemption for a waste after you have received a return receipt confirming that we have received your notification of the loss of the exemption specified in § 266.355(a) and if:

(1) You again meet the conditions specified in § 266.315 for the waste; and

(2) You send a notice, by certified delivery, to us that you are reclaiming the exemption for the waste. Your notice must be signed by your authorized representative certifying that the information provided is true, accurate, and complete. The notice must:

(i) Explain the circumstances of each failure.

(ii) Certify that each failure that caused you to lose the exemption for the waste has been corrected and that you again meet all conditions for the waste as of the date you specify.

(iii) Describe plans you have implemented, listing the specific steps that you have taken, to ensure that conditions will be met in the future.

(iv) Include any other information you want us to consider when we review your notice reclaiming the exemption.

(b) We may terminate a reclaimed conditional exemption if we find that your claim is inappropriate based on factors including, but not limited to: you have failed to correct the problem; you explained the circumstances of the failure unsatisfactorily; or you failed to implement a plan with steps to prevent another failure to meet the conditions of § 266.315. In reviewing a reclaimed conditional exemption under this section, we may add conditions to the exemption to ensure that transportation and disposal activities will protect human health and the environment.

[FR Doc. 01–11408 Filed 5–15–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261 and 268

[FRL–6975–2]

RIN 2050–AE07

Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today's action finalizes the retention of the mixture rule and the derived-from rule in the Resource Conservation and Recovery Act (RCRA), with two revisions. The mixture and derived-from rules ensure that hazardous wastes that are mixed with other wastes or that result from the treatment, storage or disposal of hazardous wastes do not escape regulation and thereby cause harm to human health and the environment.

EPA is finalizing two revisions to the mixture and derived-from rules. These revisions would narrow the scope of the mixture and derived-from rules, tailoring the rules to more specifically match the risks posed by particular wastes. The first revision is an expanded exclusion for mixtures and/or derivatives of wastes listed solely for the ignitability, corrosivity, and/or reactivity characteristics. The second revision is a new conditional exemption from the mixture and derived-from rules for ''mixed wastes'' (that is, wastes that are both hazardous and radioactive).

DATES: These final regulations are effective on August 14, 2001.

ADDRESSES: Supporting materials are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The Docket Identification Number is F–2001–WHWF–FFFFF. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling 703 603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $0.15/page. The index and some supporting materials are available electronically. See the ''Supplementary Information'' section for information on accessing them.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424–9346 or TDD 800 553–7672 (hearing impaired). In the Washington, DC, metropolitan area, call 703 412–9810 or TDD 703 412–3323.

For more detailed information on specific aspects of this rulemaking, contact Tracy Atagi, Office of Solid Waste 5304W, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0002, 703–308–8672, *atagi.tracy@epa.gov*.

SUPPLEMENTARY INFORMATION: The index and many of the supporting materials are available on the Internet. You can find these materials at <http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/index.htm>.

Affected Entities

Entities potentially affected by this action are generators of industrial hazardous waste, and entities that treat, store, transport and/or dispose of these wastes. This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action.

SIC code	NAICS code	List of potentially affected US Industrial Entities
Revision to 40 CFR 261.3 Definition of hazardous waste		
2800	32xxxx	Chemicals & allied products manufacturing.
2819	Five possible codes	Industrial inorganic chemicals manufacturing.
2821	325211	Plastics materials & resins manufacturing.
2833	325411	Medicinal chemicals & botanicals manufacturing.
2834	325412	Pharmaceutical preparations manufacturing.
2851	32551	Paints & allied manufacturing.
2869	Five possible codes	Industrial organic chemicals manufacturing.
2879	32532	Pesticides & agricultural chemicals manufacturing.
3089	Four possible codes	Plastics products manufacturing.
3241	32731	Hydraulic cement products manufacturing.
3479	Four possible codes	Fabricated metal coating & allied services
3711	Five possible codes	Motor vehicle & passenger car bodies manufacturing.
4212	562111 & 562112	Local trucking services (industrial waste shipment).
4953	Five possible codes	Refuse (industrial waste) treatment/disposal services.

SIC code	NAICS code	List of potentially affected US Industrial Entities
7389	36 possible codes	Business services.
7532	811121	Auto repair & auto paint shops.
9511	92411	Waste management.
9711	811121	National security (military bases).

Explanatory Notes:
(1) SIC= 1987 Standard Industrial Classification system (US Department of Commerce's traditional code system last updated in 1987).
(2) NAICS= 1997 North American Industrial Classification System (US Department of Commerce's new code system as of 1997).
(3) Refer to the Internet website *http://www.census.gov/epcd/www/naicsdev.htm* for additional information and a cross-walk table for the SIC and NAICS codes systems.

This table lists those entities that EPA believes could be affected by this action, based on industrial sectors identified in the economic analysis in support of this final rule. A total of about 120 entities are expected to benefit from the proposed revisions to 40 CFR 261.3 in the 17 industrial sectors listed above, but primarily in the chemicals and allied products sector (i.e., SIC code 28, or NAICS code 325). Other entities not listed in the table also could be affected. To determine whether your facility is regulated by this action, you should examine 40 CFR parts 260, 261 and 268 carefully in concert with the amended rules found at the end of this **Federal Register** document. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

ACRONYMS

Acronym	Definition
3MRA	Multimedia, Multipathway and Multireceptor Risk Assessment
APA	Administrative Procedures Act
BDAT	Best Demonstrated Available Technology
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CMA	Chemical Manufacturers Association
CWA	Clean Water Act
DOT	Department of Transportation
EPA	Environmental Protection Agency
HSWA	Hazardous and Solid Waste Amendments of 1984
HWIR	Hazardous Waste Identification Rule
ICR	Information Collection Request
IRIS	Integrated Risk Information System
LDR	Land Disposal Restriction
LLMW	Low Level Mixed Wastes
LLRWDF	Low Level Radioactive Waste Disposal Facility
MACT	Maximum Achievable Control Technology
NPDES	National Pollution Discharge Elimination System
NRC	Nuclear Regulatory Commission (NRC)
NTTAA	National Technology Transfer and Advancement Act
OMB	Office of Management and Budget
ORD	Office of Research and Development
OIRM	Office of Information and Resources Management
OSW	Office of Solid Waste
OSWER	Office of Solid Waste and Emergency Response
PBMS	Performance Based Measurement System
QA/QC	Quality Assurance / Quality Control
RCRA	Resource Conservation Recovery Act
RFA	Regulatory Flexibility Act
RfD	Reference Dose
RfC	Reference Concentration
RIC	RCRA Docket Information Center
SBREFA	Small Business Regulatory Enforcement Fairness Act
TC	Toxicity Characteristic
TCLP	Toxicity Characteristic Leaching Procedure
TDD	Telecommunications Device for the Deaf
TSDF	Treatment, Storage, and Disposal Facility
UMRA	Unfunded Mandates Reform Act
UTS	Universal Treatment Standards

Outline

Background

I. What Law Authorizes These Rules?

These rules are promulgated under the authority of Sections 2002(a), 3001, 3002, 3004, and 3006 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912(a), 6921, 6922, 6924, 6926.

II. Which Hazardous Waste Identification Rules Is EPA Finalizing Today?

Today, EPA is finalizing retention and revision of the mixture and derived-from rules, previously set forth in 40 CFR 261.3(a)(2)(iii), 261.3(a)(2)(iv) and 261.3(c)(2)(i), and proposed at 64 FR 63382 (November 19, 1999). The mixture and derived-from rules are a part of the RCRA rules that define which wastes are considered to be hazardous and therefore subject to RCRA Subtitle C rules. The mixture and derived-from rules identify as hazardous those wastes that originate from RCRA hazardous waste listed under 40 CFR part 261 (referred to as ''listed hazardous wastes''). Under the mixture rule, a mixture of a solid waste with one or more listed hazardous wastes is a hazardous waste. Under the derived-from rule, any solid waste generated from the treatment, storage, or disposal of a listed hazardous waste remains regulated as a hazardous waste. These derived-from wastes include wastes such as sludges, spill residues, ash, emission control dust, and leachate generated from listed hazardous wastes.

The mixture and derived-from rules that are being finalized today include two revisions to these rules. For the first revision, we have narrowed the applicability of the derived-from rules by excluding derivatives of wastes listed solely for the characteristics of ignitability, reactivity, and/or corrosivity when they no longer exhibit any characteristic of hazardous waste. Mixtures of wastes listed solely for the characteristic of ignitability, reactivity, and/or corrosivity which no longer exhibit any characteristic of hazardous waste continue to be excluded under today's rules. In summary, under today's final rules, all wastes listed solely for an ignitability, reactivity and/or corrosivity characteristic (including mixtures, derived-from and as generated wastes) are excluded once they no longer exhibit a characteristic.

For the second revision, we are also finalizing a conditional exemption for certain low-level mixed waste (i.e., waste that is both radioactive and hazardous) from the mixture and derived-from rules, provided the mixed waste is handled in accordance with 40 CFR part 266, Subpart N. This Subpart, which is being published as a final rule elsewhere in today's **Federal Register**, explains the eligibility requirements for this exemption, and includes several conditions and requirements for the exempted waste.

III. What Is the Legal History of These Rules?

EPA promulgated the mixture and derived-from rules in 1980 as part of the comprehensive ''cradle to grave'' requirements for managing hazardous waste. 45 FR 33066 (May 19, 1980). Numerous industries that generate hazardous wastes challenged the 1980 mixture and derived-from rules. In December 1991, the D.C. Circuit Court of Appeals vacated the rules because they had been promulgated without adequate notice and opportunity to comment. *Shell Oil Co.* v. *EPA,* 950 F. 2d 741 (D.C. Cir. 1991). The court, however, suggested that EPA might want to consider reinstating the rules pending full notice and comment in order to ensure continued protection of human health and the environment.

In response to this decision, we promulgated an emergency rule reinstating the mixture and derived-from rules as interim final rules without providing notice and opportunity to comment. 57 FR 7628 (March 3, 1992). We also promulgated a ''sunset provision'' which provided that the mixture and derived-from rules would remain in effect only until April 28, 1993. Shortly after, we published a proposal containing several options for revising the mixture and derived-from rules. See 57 FR 21450 (May 20, 1992). The May 1992 proposal and the time pressure created by the ''sunset provision'' generated significant controversy. In response, Congress included in EPA's fiscal year (FY) 1993 appropriation several provisions addressing the mixture and derived-from rules. Public Law No. 102–389, 106 Stat. 1571. First, Congress nullified the sunset provision by providing that EPA could not promulgate any revisions to the rules before October 1, 1993, and by providing that the reinstated regulations could not be ''terminated or withdrawn'' until revisions took effect. However, to ensure that we could not postpone the issue of revisions indefinitely, Congress also established a deadline of October 1, 1994 for the promulgation of revisions to the mixture and derived-from rules. Congress made this deadline enforceable under RCRA's citizen suit provision, section 7002.

On October 30, 1992, we published two notices, one removing the sunset provision, and the other withdrawing the May 1992 proposal. (See 57 FR 49278, 49280). We had received many comments criticizing the May 1992 proposal. The criticisms were due, in a large part, to the very short schedule imposed on the regulation development process itself. Commenters also feared that the proposal would result in a ''patchwork'' of differing State programs because some states might not adopt the revisions. This fear was based on the belief that States would react in a negative manner to the proposal and refuse to incorporate it into their programs if finalized. Finally, many commenters also argued that the risk assessment used to support the proposed exemption levels failed to provide adequate protection of human health and the environment because it evaluated only the risks of human consumption of contaminated groundwater and ignored other pathways that could pose greater risks. Based on these concerns, and based on EPA's desire to work through the individual elements of the proposal more carefully, we withdrew the proposal.

Subsequently, a group of waste generating industries challenged the March 1992 action that reinstated the mixture and derived-from rules without change. *Mobil Oil Corp.* v. *EPA,* 35 F.3d 579 (D.C. Cir. 1994). The court rejected this challenge, holding that the fiscal year (FY) 1993 appropriations act made the challenge moot because it prevented both us and the courts from terminating or withdrawing the interim rules before we revised them, even if we failed to meet the statutory deadline for the revisions.

We did not meet Congress' October 1, 1994 deadline for revising the mixture and derived-from rules. In early October 1994, several groups of waste generating and waste managing industries filed citizen suits to enforce the October 1 deadline for revising the mixture and derived-from rules. Two of the cases were consolidated and a third was dismissed with the plaintiffs being added as intervenor to the consolidated cases. *Environmental Technology Council* v. *Browner,* C.A. No. 94–2119, 94–2436 (TFH) (D.D.C.). The U.S. District Court for the District of Columbia entered a consent decree resolving the consolidated cases. The consent decree, as subsequently amended, required the Administrator to sign a proposal to revise the mixture and derived-from rules by November 13, 1995 and a notice of final action on the proposal by February 13, 1997, and it also specified that the deadlines in the 1992 appropriations act do not apply to any rule revising the separate regulations that establish jurisdiction over media contaminated with hazardous wastes. On November 13, 1995, the Administrator signed the proposed Hazardous Waste Identification Rule to revise the mixture and derived-from rules, which was published in the **Federal Register** on December 21, 1995. (60 FR 66344). It proposed a set of exemption levels for hundreds of hazardous constituents, many of which were based on a complex multipathway risk assessment. The notice also proposed to revise the derived-from rule to exclude wastes listed because they exhibited the characteristics of ignitability, corrosivity and/or reactivity from the definition of hazardous waste, and solicited comment on the concept of providing a separate exemption for hazardous wastes mixed with low level radioactive wastes.

We received extensive comments, many critical, on the 1995 proposal, particularly with respect to the scientific risk assessment supporting the proposed concentration-based exemption from the mixture and derived-from rules. As a result of the comments, we concluded that considerable work needed to be done to resolve the complex scientific and technical issues raised. On April 11, 1997, the District Court entered an order amending the consent decree in *Environmental Technology Council* v. *Browner.* The amended decree provided us with additional time to perform further scientific risk assessment work and required us to ask for comment on specific issues. On November 19, 1999, we published a proposal requesting comment on revisions to the mixture and derived-from rules, and discussed and requested comment on the issues specified in the consent decree. Today's final rulemaking completes our legal obligation regarding revisions to the mixture and derived-from rules.

IV. How Do the Final Rules Compare to Those Proposed on November 19, 1999?

As we proposed, we are retaining both the mixture and derived-from rules, and the revisions to those rules that we are finalizing today are for the most part the same as those we proposed in November 1999. Our rationale and basis for today's final rulemaking is set forth in Sections VII, VIII, and IX of this preamble.

The first revision amends the regulations under 40 CFR 261.3 for wastes listed in 40 CFR part 261, subpart D solely because they exhibit a characteristic of hazardous waste. Under current regulations, such listed wastes as generated or treated are considered hazardous under RCRA Subtitle C, even when the waste does not exhibit a characteristic, unless they are delisted. However, mixtures are considered non-hazardous if the waste no longer exhibits any characteristic.

In the November 19, 1999 notice, we proposed to amend the scope of and expand the applicability of the current exclusion. The notice proposed a clarifying change to the scope of the exclusion to include those wastes listed in part 261, subpart D only for a characteristic of ignitability corrosivity, or reactivity. The notice also proposed to expand the applicability of the exclusion so all these materials would be excluded from hazardous waste regulation if they are decharacterized and meet the appropriate treatment standards. The notice stated that most of the currently regulated waste eligible for this exclusion is listed as F003, but would also include certain K-, P- and U-listed wastes (See 64 FR 63390–63391, November 19, 1999).

The exclusion applies when a generator determines that the waste, whether as generated or after treatment, does not exhibit any characteristic. This exclusion is self implementing, with no additional recordkeeping and reporting requirements.[1] EPA is finalizing this exclusion as it was proposed. With respect to the applicability of land disposal restrictions (LDR) in Part 268, EPA is clarifying that when a waste has been listed solely because it exhibits a characteristic of ignitability, corrosivity, and/or reactivity AND that waste does not exhibit any hazardous waste characteristic *at the point of generation,* then that waste is not subject to the LDR requirements. Wastes that are characteristic at the point of generation and then are subsequently decharacterized are still subject to LDR requirements. For information on the major public comments and EPA's responses and rationale for this exclusion, please see Section VIII of this preamble. For discussion of the LDR issue in particular, please see Section VIII.D.

The second revision to the mixture and derived-from rules involves mixed waste (i.e., wastes that are both hazardous and radioactive). Under this revision, mixed waste is conditionally exempt from the mixture and derived-from rules, provided the mixed waste is

[1] However, under 40 CFR 268.7(a)(7)(a) generator must still put a one-time notification in the facility files describing the waste generation, regulatory exclusion, and disposition of the waste(s). According to 40 CFR 268.7(a)(8), this notification must be kept for at least three years.

handled in accordance with 40 CFR part 266, Subpart N.

The regulatory language in 40 CFR part 266, Subpart N, which we are promulgating in a separate final rule published elsewhere today, conditionally exempts hazardous waste mixed with low-level radioactive wastes (low-level mixed wastes/LLMW) from the storage, treatment in tank, transportation, and disposal requirements of RCRA. In addition, hazardous waste mixed with Naturally Occurring and/or Accelerator-produced Radioactive Material (NARM mixed waste) can be exempted from transportation and disposal requirements. The Nuclear Regulatory Commission (NRC) or its Agreement State licensed LLMW generators can store, or treat LLMW in storage tanks without RCRA Subtitle C permits if all exemption conditions are met. Treated LLMW or NARM mixed waste could be disposed at a low level radioactive waste disposal facility (LLRWDF) regulated by the NRC or its Agreement State if all exemption conditions are met. The rationale for conditionally exempting LLMW from the mixture and derived-from rules is the same as that for creating the conditional exemption from the RCRA regulatory definition of hazardous waste for LLMW.

We are largely finalizing the mixed waste exemption from the mixture and derived-from rules as proposed. However, to address public comments on the need for more clarity of this exemption, we have revised the regulatory language and have moved it to its own subsection (40 CFR 261.3(h)). As used in section 261.3(h), the term ''eligible radioactive mixed waste'' refers to hazardous waste containing radioactive waste that meets the eligibility criteria and conditions of part 266, subpart N. In addition, we have made some changes to the new Subpart N from what we proposed. Those changes are explained in the mixed waste final rule, published elsewhere in the **Federal Register** today. For information on the public comment regarding the exemption, and EPA's responses please see Section IX of this preamble.

V. When Will the Final Rules Become Effective?

Today's rules become effective August 14, 2001. Pursuant to section 3010(b)(1) of RCRA, the Administrator finds that the regulated community does not need six months to come into compliance with today's rulemaking, because today's action retains rules already in effect, and expands an exclusion that reduces regulatory burden.

VI. What Other Changes to the Hazardous Waste Identification Rules Is EPA Continuing To Pursue?

EPA continues to pursue an exemption from hazardous waste management that we discussed in the November 19, 1999 HWIR **Federal Register** notice (64 FR 63382). That exemption, also known as the Hazardous Waste Identification Rule (HWIR) exemption, would exempt listed hazardous wastes that meet chemical-specific exemption levels [2] from the definition of hazardous waste. The HWIR exemption would help address concerns that the mixture and derived-from rules result in over-regulation, since listed hazardous waste remains under Subtitle C jurisdiction regardless of constituent concentration or presence in the waste, either before or after treatment. This concern was exacerbated with the passage of HSWA in 1984. HSWA set Land Disposal Restrictions (LDR) requiring best demonstrated available technology (BDAT) treatment for all listed hazardous wastes prior to disposal. In cases where a specific listed wastestream contained relatively innocuous constituents, or very low concentrations, BDAT treatment requirements were felt to be overly protective, and unnecessarily expensive. The Agency believes that an HWIR exemption process would help reduce the potential over-regulation of low risk hazardous waste while, at the same time, reducing the time and resource burden on industry and government. An exemption process would also reduce the burden on the ongoing delisting program. In the 1995 HWIR proposal, we estimated cost savings ranging from $75 million to $99 million, based on exemption levels proposed at that time. Given that the modeling for exemption levels is undergoing major revision, it is not possible at this time to estimate the cost savings from a future constituent-based exemption.

We plan to develop the HWIR exemption levels based on results from the Multi-media, Multi-pathway and Multi-receptor risk assessment (3MRA) Model. The model evaluates simultaneous chemical exposures across several environmental media and multiple exposure pathways to human and ecological receptors in order to estimate the health and ecological effects in the vicinity of waste disposal units that may receive exempt listed hazardous waste. We presented the underlying methodology and assumptions for the 3MRA Model in the **Federal Register** (64 FR 63382, November 19, 1999). However, because of technical difficulties arising from the complexity of the modeling effort, we were unable to propose exemption levels in that notice. Since then, we have made numerous revisions to correct and improve the model.

On July 18, 2000, EPA made available in a Notice of Data Availability (NODA) the model results for 36 chemicals, using an updated version of the model (65 FR 44491). The NODA, and referenced background information placed in the docket, explained technical changes made to the model since the November 19, 1999 **Federal Register** notice. Finally, the NODA extended the comment period for the November 19, 1999 HWIR exemption discussion until October 16, 2000.

We are currently reviewing the public comments and will decide if further revisions to the HWIR risk assessment (3MRA) model are necessary. We also are continuing independent testing and external peer review of the HWIR risk assessment model.

In addition to the HWIR risk assessment, the November 19, 1999 **Federal Register** notice discussed options for implementing the HWIR exemption. We also plan to review the comments relating to implementation. Before using the revised risk assessment to support a final rulemaking on the HWIR exemption, we will publish a proposal to allow public comment on a unified package.

In another effort to better calibrate risk and regulatory standards, the Agency is also developing two targeted exemptions from the hazardous waste mixture and derived-from rules: one for certain solvents destined for wastewater treatment and discharge under the Clean Water Act, and another for slagged combustion residues from hazardous waste combustors. Other targeted exemptions are being assessed for later development (see Section X of this preamble for further discussion). We also plan to continue on-going efforts to streamline the existing delisting process.

Major Comments

VII. What Were the Major Comments on Retaining the Mixture and Derived-From Rules, and How Has EPA Responded to Them?

EPA received several dozen comments on the issue of retaining the mixture and derived-rules for both the 1995 and 1999 HWIR proposals. Below is a summary of three major issue areas

[2] An ''exemption level'' in this context is a specific chemical concentration. If all chemicals in a waste are below their exemption levels, then the waste would be considered non-hazardous.

raised in the comments, and EPA's responses. For more detailed comment responses, please see *Hazardous Waste Identification Rule: Revisions to the Mixture and Derived-From Rules Response to Comments Document.*

A. Need for the Mixture and Derived-From Rules

(1)(a) Summary of the Comments on the Need for the Mixture and Derived-From Rules

EPA received comments from 38 commenters in response to both the 1995 and the 1999 HWIR proposals specifically concerning the necessity of the mixture and derived-from rules. Of those comments, 14 were received from industry, seven were from industry associations, eight were from State Agencies, five were from waste management companies, two were from waste management associations, one was from a Federal Agency and one was from a consultant.

The States and waste management associations supported the retention of the mixture and derived-from rules, while the industry commenters generally believed that the mixture and derived-from rules were unnecessary. A summary of the specific issues raised by commenters is provided below.

Twelve commenters explicitly supported the retention of the mixture and derived-from rules. Many of the State commenters said that the rules were necessary to capture mixtures and derivatives of listed hazardous wastes in the universe of regulated hazardous wastes in order to protect human health and the environment. The commenters noted that without these rules, it would be possible to alter a particular waste to the point that it no longer meets the listing description without detoxifying, immobilizing, or otherwise actually treating the waste. One industry association commenter also supported the retention of the mixture and derived-from rules, noting that although it is not a perfect solution, the approach has been used for the last 15 years in a generally effective manner.

One waste management association commenter also strongly supported the retention of the mixture and derived-from rules. The commenter believed the mixture and derived-from rules were necessary because they prevented many wastes that clearly were hazardous and that posed substantial threats to human health and the environment from escaping RCRA controls only because they are mixtures or derivatives that no longer fit an original listing description. The commenter noted that generators send their listed hazardous wastes to treatment facilities for initial treatment to reduce the toxicity and/or mobility of some, but not all, toxic constituents in the waste. The commenter also agreed that EPA's experience with delisting petitions further supported the rationale for the mixture and derived-from rules.

Twenty-six commenters did not support the retention of the mixture and derived-from rules. Some asserted that eliminating the derived-from rule would be a common sense reform of RCRA to reduce unnecessary over-regulation of many wastes. Many industry commenters and industry associations commented that the mixture and derived-from rules unnecessarily continue to regulate low-risk material resulting in significant waste management costs with no associated environmental benefit, thus also affecting the credibility of EPA. Several of the comments cited EPA's 1992 HWIR proposal, saying that ''millions of tons of mixtures and derived-from residuals that must be managed as hazardous waste * * * may actually pose quite low hazards.'' (57 FR 21451, May 20, 1992). The Department of Defense acknowledged the need to retain the mixture and derived-from rules; however, the commenter noted that the mixture and derived-from rules have been a source of over-regulation for low-risk wastes.

Several commenters asserted that the mixture and derived-from rules have no continued viability, particularly in light of the technological advances that have developed since the rules were first promulgated in 1980. They noted that since 1980, the regulated community has made considerable improvements in the treatment, storage, and disposal of hazardous waste. In their view, the result is that the risks that formerly may have been associated with the management of hazardous waste have been reduced significantly or eliminated, such that the universe of waste that may have warranted Subtitle C regulation in 1980 has been reduced significantly. Six commenters agreed with the U.S. Court of Appeals observation in *Shell Oil Co.* v. *EPA,* 590 F.2d 741, 752 (D.C. Cir. 1991) that, ''the derived-from rule becomes counterintuitive as applied to processes designed to render wastes nonhazardous. Rather than presuming that these processes will achieve their goals, the derived-from rule assumes their failure.'' Commenters also noted that the hazardous waste characteristics, particularly the Toxicity Characteristic, would continue to ensure proper management of high risk wastes under RCRA.

Several commenters stated that when compared to established standards, a waste material is either hazardous or it is not and it is not necessary to consider the origin of the material. The consultant noted that the mixture rule is completely unnecessary and isn't scientifically appropriate because if the compound or element in the waste needs to be controlled in a certain environment, it doesn't matter what the source is. Therefore, a regulation should set the limit for that environment for that compound or element and the mixture and derived-from rules should be eliminated. One commenter believed that the continued inflexible application of the mixture and derived-from rules has served only to bring to light the self-defeating complexity of the program.

(1)(b) EPA Response To Comments on the Need for the Mixture and Derived-From Rules

EPA acknowledges that the mixture and derived-from rules apply regardless of the concentrations and mobilities of hazardous constituents in the waste. We have implemented and will continue to pursue actions to reduce any overregulation of low-risk wastes arising from the mixture and derived-from rules. Nevertheless, EPA believes that retention of the mixture and derived-from rules are necessary to ensure protection of human health and the environment. When EPA determines that a waste should be listed as hazardous, we consider several different factors, including the toxicity of the chemicals in the waste, the persistence of those toxic chemicals, and the degree to which the chemicals bioaccumulate in the environment. As discussed below, the act of mixing a hazardous waste with another waste, or storing, treating, and disposing of that waste does not necessarily remove the hazard posed by these toxic chemicals. Under RCRA, EPA has an obligation to ensure that the risk posed by a hazardous waste is controlled from the cradle to the grave. Both the mixture and derived-from rules are needed to make sure that this obligation is carried out.

Concerns About Deliberate Evasion

When EPA originally promulgated the mixture and derived-from rules in 1980, one of our main concerns was that, without these rules, generators could deliberately evade regulation by taking advantage of a ''loophole'' in the hazardous waste identification process. (45 FR 33084, 33095 (May 19, 1980)). Specifically, we believed that without the mixture and derived-from rules, generators could potentially alter their waste so that it no longer meets the

listing description without detoxifying, immobilizing, or otherwise effectively treating the waste.

Despite the progress that has been made in environmental compliance in the past twenty years, this concern remains, and the comments of EPA's co-regulators, the State governments, echo this continuing concern. EPA agrees with those industry comments that claim many companies are more environmentally aware and responsible than they were in the past. However, there will always be some entities who might try and exploit gaps in the regulatory system. Absent the mixture and derived-from rules, there would be a potentially significant gap in the coverage of the hazardous waste listings.

For example, without a ''mixture'' rule, generators of hazardous wastes could potentially evade regulatory requirements by mixing listed hazardous wastes with other hazardous wastes or nonhazardous solid wastes to create a ''new'' waste that arguably no longer meets the listing description, but continues to pose a serious hazard. Similarly, without a ''derived-from'' rule, hazardous waste generators and hazardous waste treatment, storage, and disposal facilities (TSDFs) could potentially evade regulation by minimally processing or managing a hazardous waste and claiming that the resulting residue is no longer the listed waste, despite the continued hazards that could be posed by the residue even though it does not exhibit a characteristic. A hazardous waste regulatory system under which it could be argued that hazardous waste could leave the system as soon as it was modified to any degree by being mixed or marginally treated would be ineffective and unworkable. Such a system could act as a disincentive to adequately treat, store and dispose of listed hazardous waste.

In addition, as explained below, even if generators or TSDFs do not deliberately try to evade hazardous waste regulations, certain waste mixtures and derived-from wastes could pose substantial present or potential hazards if mismanaged. We, therefore, continue to believe that the mixture and derived-from rules are necessary to capture wastes that would pose unacceptable risks to human health and the environment.

Regulating Hazardous Waste Mixtures

Mixing hazardous waste with another waste may dilute, and sometimes mask, the concentrations of toxic constituents in the listed waste, but does not necessarily address the hazards posed by these constituents. Some of the comments focused on diluted wastewaters as an example of mixtures that are potentially ''low risk.'' Of the ''millions of tons'' of waste that EPA estimated would be exempted under the 1995 HWIR proposal because they may pose low risks, 99% of the waste by volume is wastewater (60 FR 66415, December 21, 1995). Wastewaters are generally disposed either in an underground injection control well regulated under the Safe Drinking Water Act (SDWA)or to the environment under the Clean Water Act (CWA). Because discharged hazardous wastewaters must meet CWA standards, some commenters believe that these wastewater mixtures should be excluded from hazardous waste regulation prior to their discharge.

We have several concerns with this argument. The management of wastewater mixtures is already largely exempt from most RCRA requirements. The two main requirements that remain under RCRA are that the wastewaters must be managed in tanks, and the treatment sludge must be managed as a hazardous waste once removed from the tank. Continued management of these wastewaters in tanks is usually needed to avoid infiltration to groundwater of concentrations of toxic constituents that pose unacceptable risks. Even when they meet their CWA discharge limits, mismanaged wastes could pose unacceptable risks through the groundwater pathway, which is not addressed by the CWA. Sludges from wastewater treatment need to be managed as hazardous waste, because they can contain the same persistent and toxic chemicals (e.g., heavy metals) that originated in the wastewaters. Each of these points is discussed in more detail below.

RCRA section 1004(27) already excludes industrial wastewater discharges subject to CWA section 402 regulation from the definition of ''solid waste'' under RCRA. See also, 40 CFR 261.4(a)(2). In addition, wastewater treatment units, as defined in 40 CFR 260.10 (i.e., tanks), are excluded from almost all RCRA regulation (see 40 CFR 264.1(g)(6); 265.1(c)(10); and 270.1(c)(2)(v)). RCRA has historically deferred to the Clean Water Act and its oversight in properly regulating hazardous wastewaters discharged by CWA wastewater treatment systems or other point sources subject to CWA discharge requirements, including storage in wastewater treatment units prior to discharge. However, with the exception of sewage sludge, the CWA does not apply to sludges which are a byproduct of wastewater treatment. To the extent treatment of listed hazardous wastewaters generates sludges, those sludges are considered hazardous by the derived-from rule (as discussed below).

Furthermore, to the extent that additional hazards may be associated with wastewaters managed in such systems (including risks via inhalation pathway and risks via groundwater ingestion when treatment takes place in surface impoundments),[3] the Agency considers such wastes as hazardous and within RCRA jurisdiction until discharged. While wastewaters must meet CWA requirements at the point of discharge, they can still have high concentrations of constituents during the management of the waste.

Even after hazardous wastewaters have been treated to meet CWA standards, they could still have the potential to pose unacceptable risks to human health and the environment when managed in surface impoundments or other retention ponds (or otherwise managed on the land, i.e., during a spill) prior to discharge to the receiving water body. Both surface impoundments and retention ponds can have high potential for discharge of the wastewaters they contain to underlying groundwater (*see* RCRA sections 1002(b)(7) and 3005(j)). Discharge treatment requirements based on State water quality standards are calculated by taking the nature of the effluent and the receiving water body into account. An effluent treated to meet water quality standards for a surface water body could leach into groundwater, depending on the hydrogeology of the site, if subsequently held in a surface impoundment or retention pond prior to discharge. This leachate could undergo a lesser degree of dilution in groundwater than in the intended surface water body, potentially posing unacceptable risks to groundwater users through a drinking water well. This risk is not accounted for under the current federal CWA standards.[4] Therefore, EPA continues to believe that retaining

[3] The Revised Air Characteristic Study (EPA 530–R–99–019a) published August 1999 suggests that potential risks emanating from wastewaters managed in wastewater treatment tanks may be of regulatory concern and may represent a regulatory gap because of the existing exclusions for wastewater treatment units from control requirements.

[4] The current federal National Pollution Discharge Elimination System (NPDES) program under the CWA does not require permitting authorities to issue permits for discharges of wastewater to groundwater (See 40 CFR 122.1 and 122.2). The exception is those instances in which a discharge to surface water may occur via a hydrologic connection between a groundwater and surface water. In addition, some states have chosen to exceed federal program requirements and do issue such permits. *See also* U.S. EPA NDPES. Permit Writers' Manual, United States Environmental Protection Agency, Office of Water, December 1996. EPA–833–B–96–003.

jurisdiction over hazardous wastewaters under RCRA prior to their NPDES-permitted discharge is necessary to ensure protection of human health and the environment.

Another reason why these wastewaters should not be categorically designated as non-hazardous prior to discharge is because that would effectively exclude their treatment sludges as well (by avoiding the application of the derived-from rule).[5] As explained below in more detail, treatment sludges from these dilute wastes cannot be assumed to be low risk. In fact, treatment sludges can contain high levels of the very chemicals (e.g., heavy metals) that caused the original waste to be listed. In these cases, the hazard that was identified as the original basis of listing has not been removed; it has merely been transferred to another type of waste matrix (i.e., from a water to a solid).

In sum, EPA has excluded (through the wastewater treatment unit exclusions) hazardous wastewaters from regulation where we believe there is a reasonable basis to do so, grounded in the protection of human health and the environment, and the statute excludes from RCRA jurisdiction industrial wastewater discharges subject to CWA discharge permits. But based on the available data, EPA believes that a blanket wastewater exclusion from regulation is not warranted. Instead, EPA will continue to develop approaches (e.g., targeted exemptions and HWIR exemption levels) to address wastewaters that are be considered low risk.

Regulating Derived-From Wastes

As explained in 40 CFR 261.3(c)(2)(i), any solid waste derived from the treatment, storage, or disposal of a hazardous waste is also considered a hazardous waste. Specific examples of these derived-from wastes include sludges, spill residues, ash, emission control dust, and leachate. For derived-from wastes that change location but are otherwise unmodified, the question of their continued regulation is more straightforward. Because such waste would have the same levels of toxic constituents and presumably the same potential exposure patterns as the waste that was evaluated for the original hazardous listing determination, it would pose the same unacceptable risk as the original waste.

Other types of derived-from wastes may have a different physical form than the original waste, but still present the same chemical hazard. Leachate derived from the disposal of hazardous waste, for example, can contain the same chemicals as found in the original waste. When EPA analyzed leachate for purposes of promulgating effluent guidelines for landfill leachate (65 FR 3007, January 19, 2000), we found that wastewater generated as a result of a particular industrial operation can have a similar pollutant profile to leachate generated by a landfill receiving the bulk of their waste from that same operation (65 FR 3008, 3012, January 19, 2000). During treatment, chemicals in hazardous wastewater are transferred to the sludge, which is disposed of in the captive landfill. Once the sludge is disposed in a landfill, persistent chemicals in this sludge can then transfer to the leachate, which, when managed in a wastewater treatment unit, transfers them once more to sludge. Although changed in form, the treatment sludge (and leachate) could still pose similar unacceptable risks as the originally listed waste, depending on actual concentrations and exposure patterns.

We also found considerable differences between the leachate samples from hazardous and those from non-hazardous waste landfills in both numbers of constituents of concern and their concentrations. Hazardous waste landfill leachate contained a greater number of constituents than non-hazardous waste landfill leachate, and constituents found in both hazardous and non-hazardous waste landfill leachate were generally present in hazardous waste landfill leachate at concentrations an order of magnitude higher than those found in non-hazardous waste landfill leachate.[6] Absent a risk assessment, it is not possible to determine whether the levels of these constituents pose unacceptable risk. However, the presence of such constituents creates a continuing concern regarding leachate derived from hazardous waste.

The other broad category of derived-from waste are treatment residues. At least six commenters cited the D.C. Circuit Court of Appeals observation in *Shell Oil Co.* v. *EPA,* 590 F.2d at 752 that ''the derived-from rule becomes counterintuitive as applied to processes designed to render wastes nonhazardous.'' However, the presumption that treatment always renders hazardous waste nonhazardous is overly simplistic. This presumption does not take into account all products of treatment. Even treatment that operates properly is often designed to isolate a hazardous residual. For example, wastewater treatment designed to produce a sufficiently clean effluent for discharge is also designed to move the hazardous constituents from the wastewater into the sludge. The resulting de-watered sludge, while much lower in volume than the original hazardous wastewater, has the potential to have much greater concentrations of hazardous chemicals. As explained above, once the sludge is disposed in a landfill, persistent chemicals in this sludge can then transfer to the leachate, which, when managed in a wastewater treatment unit, transfers them once more to sludge.

The derived-from rule thus ensures that the chemicals in the originally listed waste that are transferred to another matrix when the waste is managed remain under RCRA Subtitle C control. Without the derived-from rule, a hazardous wastewater could be treated so that hazardous constituents are moved to the sludge. If the generator could claim that the resulting sludge, regardless of chemical concentration, no longer meets the listing description, then that sludge could be handled as non-hazardous waste, and placed in an unlined industrial landfill, or sent to a land application unit.[7] The resulting leachate would not necessarily be collected. Instead, those chemicals that first caused the waste to be listed could potentially now enter the environment and, depending on the actual chemical concentrations and exposure patterns, could pose unacceptable risks.

Other types of treatment, which result in combining wastes with different chemical concentrations, can result in dilution of those chemicals, but may not adequately address the hazard they could pose. As mentioned earlier in the discussion on regulating mixtures, combining wastewaters for centralized treatment is often a legitimate treatment practice, but the diluting effect of such treatment does not address the transfer of persistent chemicals to the sludge.

Finally, treatment that reduces the amount of organic chemicals in a waste does not typically address the risk from

[5] These wastes would still be subject to the hazardous waste characteristics of 40 CFR Part 261, Subpart C, but, as explained later in this preamble section, such coverage would not address all the unacceptable risks potentially posed by the chemicals in these wastes.

[6] Development Document for Final Effluent Limitations Guidelines and Standards for the Landfills Point Source Category, EPA–821–R–99–019, U.S. EPA, January 2000.

[7] These wastes would still be subject to the hazardous waste characteristics of 40 CFR Part 261, Subpart C, but, as explained later in this preamble section, such coverage would not address all the unacceptable risks potentially posed by the chemicals in these wastes.

metals in the waste. For example, biological treatment and incineration, which are among the most aggressive forms of treatment, are designed to reduce or destroy organic chemicals. However, these types of treatment do not address heavy metals and may form chemical by-products (e.g., dioxins) that could pose unacceptable risks, if not managed properly. For example, baghouses on combustion devices serve to collect hazardous constituents that would otherwise be emitted to the air from the combustion process, and the dust that is removed from the baghouses predictably contains metals that were in the original waste. In response to industry comments, EPA will explore specific approaches for dealing with biological treatment residues and has already begun considering an alternative approach to address combustion residues (See Sections X.C. and X.D. of this preamble.) EPA will also continue to develop approaches (e.g., targeted exemptions and HWIR exemption levels) to exempt other waste streams that are currently captured by the derived-from rules but pose low risks.

Historic Information on Mixture and Derived-From Wastes

As we discussed in the 1999 proposal, EPA's experience with the delisting program further supports retaining the mixture and derived-from rules as a necessary part of hazardous waste identification. Generators can petition EPA under 40 CFR 260.22 to exclude a waste produced at a particular facility from the definition of hazardous waste. Such petitions must demonstrate that the waste does not meet any of the criteria for which it was listed nor has other attributes that might result in the waste being hazardous.

Over the 20-year period from 1980 through 1999, EPA reviewed over 900 petitions to delist wastes, and granted delistings to 136 waste streams generated at 115 separate facilities. Most of the petitions (i.e., more than 600) were withdrawn or mooted before the review was complete; 108 were denied. Most of these denials were based on lack of information. In at least 13 of the 36 cases where enough information is available in the source documentation to determine whether a waste was a mixture or derivative, we denied delisting petitions for mixtures or residuals of listed waste because risk analyses indicated that the toxicity and leaching potential of hazardous chemicals in those wastes posed unacceptable risk to human health. These mixture and derived-from wastes had potentially hazardous levels of a wide range of chemicals including barium, cadmium, chromium, lead, mercury, nickel, benzene, benzo(a)pyrene, cyanide, chloroform, 1,1-dichloroethane, 1,1-dichloroethylene, 2,4-dinitrotoluene, methylene chloride, trichloroethylene, and vinyl chloride.[8]

We have also identified possible damage cases associated with mixture and derived-from wastes. For example, there are Superfund sites that contain mixture and derived-from wastes (See 50 FR 658). We have identified at least twenty sites that may have involved the mismanagement of mixture and derived-from wastes.[9] The sites identified include cases of extensive contamination of soils and groundwater with metals (e.g., arsenic, lead, mercury), cyanide, and organics (e.g., benzene, toluene, and xylenes). It is very difficult to identify the full range of damage cases that specifically involve waste mixtures or derivatives since neither EPA nor other parties track or categorize waste based on its status under the mixture or derived from rules.

The legislative history of RCRA also provides examples of damage cases caused from disposal of mixture and derived-from hazardous wastes. In introducing the purpose of Subtitle C, the House Committee on Interstate and Foreign Commerce cited seven pages of damage cases, stating, ''The most effective way of illustrating the dangers of improper hazardous waste disposal is perhaps to cite actual instances of damage caused by current hazardous waste disposal practices. The following section is merely illustrative of the problem. Far more cases could be cited, even more have gone unreported.'' H.R. Rep. No. 94–1491 (94th Cong. 2d Sess. 1976) 17–23. Of the 59 instances described in the House Committee Report, at least 40 involved spills, leachate or runoff from landfills, lagoons or waste storage facilities. Leachate and run-off are derived-from wastes, as are spills from storage and disposal facilities, and some of the sources contained mixtures of hazardous and non-hazardous solid wastes.

Intrinsic Chemical Properties of RCRA Hazardous Waste ''Mixtures'' and ''Derived-From'' Wastes

We also analyzed the information in EPA's National Hazardous Waste Constituent Survey (NHWCS) Database to assess the intrinsic physical and chemical properties of RCRA hazardous waste ''mixtures'' and ''derived-from'' wastes. The purpose of the NHWC Survey was to collect descriptive information about the identity and measured concentrations of chemical constituents contained in RCRA hazardous wastes. The NHWCS was a one-time, voluntary participation mail survey we administered in 1996, providing a single-year ''snapshot'' of the intrinsic physical and chemical properties of RCRA hazardous wastes. It is EPA's most comprehensive and current database about hazardous waste constituents. We benchmarked the 1996 survey to data already collected in our 1993 Biennial Reporting System (BRS) database—which contains data provided by the 1993 universe of RCRA hazardous waste large quantity generators—by pre-loading survey questionnaires with the known 1993 BRS data for the NHWC survey facilities, and asking facilities to verify the known BRS data, as well as to provide new data about the known chemical constituents in the RCRA hazardous wastes they managed (constituent data are not contained in the BRS database). This analysis is presented as a technical supplement to this rulemaking for purpose of public understanding of the intrinsic nature of these two groups of wastes, which we currently regulate as RCRA hazardous. This supplemental analysis corroborates the substance of our proposed rule (64 FR 63382–63461, Nov. 19, 1999).

Although the survey results apply to a subset of the total universe of waste and should not be extrapolated to the larger universe of RCRA hazardous waste generators, the information provides valuable insight into the types and levels of chemicals that could be present in such wastes. A large number of waste streams captured in the NHWCS were identified by their generators as mixtures of solid waste and hazardous waste or derived-from hazardous wastes. The analysis revealed that potentially hazardous chemical constituents, have been and can be present in wastes mixed with or derived-from, RCRA hazardous wastes. Although this analysis is not a quantitative risk assessment, this conclusion is supported by the presence of persistent, bioaccumulative, and toxic (PBT) chemicals in these two waste groups, some of which are at relatively high concentrations. Consequently, we continue to be concerned about the potential risks posed by the mismanagement of RCRA hazardous

[8] U.S. EPA *Evaluation of Hazardous Waste Delisting Program,* December 2000; and *Analysis of the Delisting Petition Data Management System,* U.S. EPA, September 1998). EPA Docket 99–WH2P–FFFFF.

[9] EPA 2000. *Releases of Hazardous Constituents Associated with Mixture and Derived-from Wastes (An Update)* U.S. EPA, April 2000.

waste ''mixtures'' and ''derived-from'' wastes.

For more information about this analysis, please see the background document *Analysis of RCRA ''Mixtures and Derived-from'' Hazardous Waste Constituent Data,* which is available to the public from the RCRA Docket. The NHWCS database is available to the public via the Internet at *http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/economic.htm.*

Regulatory Coverage by the Toxicity Characteristic

EPA also does not agree with comments that the mixture and derived-from rules are not necessary because the Toxicity Characteristic (TC) provides regulatory coverage of these wastes. The TC currently sets regulatory levels for only 40 chemicals. (see 40 CFR 261.24). On the other hand, the hazardous waste listings are based on hundreds of different chemicals. (see Appendix VII to 40 CFR Part 261). In addition, the TC levels are the result of laboratory analyses to predict whether a waste is likely to leach chemicals into groundwater at hazardous levels, not the result of a comprehensive risk assessment. Depending on the actual constituents in a waste and their concentrations, wastes with constituents that fall below TC levels can still pose unacceptable risks to human health and the environment if mismanaged. (55 FR 11799). EPA has listed wastes based on the presence of constituents below the TC levels. For example, in the final listing decision for spent hydrotreating and hydrorefining catalysts from refinery operations, we analyzed the potential risk from arsenic and benzene using input leachate concentrations capped at TC regulatory levels. The results of this analysis suggested unacceptable risks posed by these wastestreams from concentrations below the TC regulatory levels (63 FR 42154). The mixture and derived-from rules are necessary for capturing such wastes that could pose unacceptable risks from chemicals without TC levels and for risks not addressed by the TC approach.

Conclusion

When EPA determines that a waste is capable of posing a hazard to human health or the environment when improperly managed, that determination is based on consideration of several different factors, including the toxicity, persistence, degradability in nature, the potential of chemicals to bioaccumulate in tissue, flammability, corrosiveness, and other hazardous characteristics and related factors. The act of mixing, storing, disposing or even treating the waste does not guarantee removal of the hazard posed by these chemicals, nor does it remove EPA's obligation to ensure that the hazards presented by the waste continue to be controlled from the cradle to the grave, even when it is transferred to another waste matrix. Nevertheless, EPA will continue to develop approaches to exempt low-risk wastes from full Subtitle C regulation, as appropriate. Since the original promulgation of the mixture and derived-from rules, we have invited suggestions as to better ways of handling the difficult issues associated with the mixing, treating, storing, disposing, and otherwise managing waste following its generation. See 45 FR 33095 (May, 19, 1980). We have considered and are continuing to pursue suggestions for targeted exemptions (e.g., the CMA suggestions discussed at Section X of the preamble) as well as a risk-based exit level approach to identifying low-risk wastes.

B. Legality of the Mixture and Derived-From Rules

EPA received comments in response to both the 1995 and 1999 HWIR proposals on RCRA Subtitle C jurisdiction over mixtures and derivatives from the management of listed hazardous wastes. Of the 42 commenters who specifically commented on the statutory authority for these rules, 38 were received from industry (including utilities and trade associations), two were from waste management companies, one was from a waste management association and one was from an individual commenter. Almost all these comments expressed the view that EPA lacked statutory authority to promulgate these rules, although other commenters who generally supported retention of the mixture and derived-from rules expressed the view that these wastes are properly under RCRA Subtitle C jurisdiction.

The waste management association agreed that EPA had statutory authority under RCRA to promulgate the mixture and derived-from rules in 1980, and that EPA also had ample authority to retain the basic rules now without change. The commenter, citing *Shell Oil Corp.* v. *EPA,* believed that the rules were consistent with EPA's legal authority under RCRA section 3001 to determine when wastes are hazardous based on listing criteria, and under RCRA sections 3002–3004 to impose regulatory standards until wastes have ceased to pose a hazard to the public.

As noted, most commenters expressed the view that EPA is acting beyond its statutory authority by retaining the mixture and derived-from rules. These comments asserted three main points: (1) Mixture and derived-from wastes do not meet the statutory definition of hazardous under RCRA section 1004(5); (2) EPA has not met the requirements under section 3001, 42 U.S.C. Section 6921 and 40 CFR 261.10 and 261.11 for designating wastes as hazardous; and (3) EPA has no authority under sections 3002–3004 of RCRA to designate wastes as hazardous. A summary of each of these specific issues raised by commenters, and EPA's response to these issues, is provided below. For more information on these comments and EPA' responses, please see *Hazardous Waste Identification Rule: Revisions to the Mixture and*

Derived-From Rules Response to Comments Document.

(1)(a) Comment: Mixture and Derived-From Wastes Do Not Meet the Statutory Definition of Hazardous Under RCRA Section 1004(5)

Numerous commenters from industries, industry associations, utility companies, utility company associations and waste management companies generally believed that the mixture and derived-from rules were too broad and swept in many wastes which did not meet the statutory definition of hazardous wastes, and that the derived-from rule in particular was not supported by statutory authority. One commenter even felt that the derived-from rule was a ''legal fiction'' because treatment residuals must be managed as if the treatment had not occurred. Commenters noted that EPA only was authorized under the Resource Conservation and Recovery Act (RCRA) to designate as hazardous waste those solid wastes that EPA determined may (1) cause, or significantly contribute to an increase in mortality or serious illness, or (2) pose a substantial present or potential hazard to human health or the environment when improperly managed (RCRA section 1004(5), 42 U.S.C. 6903(5)). Commenters expressed the view that EPA can regulate under Subtitle C only those solid wastes that EPA determined pose substantial hazards per the language in Section 1004(5) of RCRA. Many commenters also noted that, in their view, many of these wastes pose minimal or no threat to the environment and public health. The majority of these commenters believed that EPA made no attempt to demonstrate that derived-from wastes met the statutory definition of hazardous waste. Instead, these commenters believed EPA simply drew conclusions that these materials were

hazardous waste, even though many derived-from wastes had not met the statutory definition of hazardous waste. They also noted that EPA has admitted that many derived-from wastes pose little risk to human health or the environment. Therefore, they claim that the derived-from rule was not a legally valid approach to regulating materials that result from the management of hazardous waste.

(1)(b) EPA Response

While we agree that the mixture and derived-from rules capture some waste that may actually pose quite low hazard, we have implemented and continue to pursue approaches (such as today's revisions) to exclude such waste from full Subtitle C regulation. Nevertheless, these rules are a necessary component of cradle-to-grave waste management, to protect human health and the environment from unacceptable risks. EPA does not agree with comments that mixtures and derivatives do not meet the definition of ''hazardous waste'' in section 1004(5) of RCRA, nor do we agree that Congress did not intend these wastes to be regulated under Subtitle C of RCRA.

The definition of hazardous waste is a broad definition which encompasses solid wastes or combinations of solid wastes which, because of their ''quantity, concentration, or physical, chemical, or infectious characteristics may * * * pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed.'' Because they originate from waste that has already been determined to be hazardous, EPA has a reasonable basis to conclude that mixtures and derivatives could also pose a potential or present hazard to human health or the environment if not properly managed. The original listing of the waste already establishes the reasons, i.e., the ''quantity, concentration, or physical, chemical, or infectious characteristics'' for having identified the listed waste as hazardous. It is reasonable to conclude, without information to the contrary, that both mixtures and derivatives of such wastes may pose a substantial potential or present hazard to human health or the environment if not properly managed, and therefore fall under the definition of hazardous waste in RCRA section 1004(5).

Nothing in the section 1004(5) definition of hazardous waste requires EPA to prove that every member of a category of waste poses a hazard. In fact, many waste listings describe categories or ''classes'' of hazardous wastes because they cover a range of materials that are not identical in composition.

EPA also does not agree with commenters' assertion that wastes derived from the treatment, storage, or disposal of listed hazardous wastes in particular do not meet the section 1004(5) definition. As explained in section VII.A.2, residuals from the treatment of hazardous wastes can contain higher concentrations of the chemicals that led to the hazardous waste listing in the first place, and therefore may pose a present or potential hazard to human health or the environment if improperly managed. Indeed, the objective of many forms of treatment is precisely to isolate and collect hazardous constituents, often in concentrated form, for further management. For example, de-watering of waste, e.g., to make it easier to transport, is a form of treatment that often does not significantly change the character of the waste other than to leave it in a more compact and concentrated form. At the more aggressive end of the treatment spectrum, baghouses on hazardous waste combustion devices collect hazardous constituents that would otherwise be emitted to the air from the combustion process, creating dust that predictably contains any metals that were in the original wastes as well as products of incomplete combustion. Congress specifically expressed concern in RCRA about treatment residues created by federal and state pollution control laws, RCRA 1002(b)(3). The potential for persistent hazardous constituents in treatment residues and the Congressional findings in the RCRA statute support EPA's conclusion that residuals from the treatment, storage and disposal of listed hazardous waste may pose a substantial present or potential hazard.

EPA acknowledges that not all mixtures and derivatives pose hazards to human health and the environment (see, e.g. 57 FR 21451). There are mechanisms to address this fact, and we are continuing to pursue approaches to exempt low-risk wastes. First, RCRA and EPA regulations provide for the delisting of listed hazardous waste. RCRA 3001(f); 40 CFR 261.20 and 40 CFR 261.22. Since the federal delisting program took effect in 1980, EPA has excluded an estimated 45 million tons of waste, resulting in an estimated cumulative cost savings between $1.1 billion and $1.3 billion dollars (in 1999 dollars). In 2000 alone, we estimate cost savings of approximately $105.4 million.[10] In the 1995 HWIR proposal, EPA stressed the continued need for the delisting program, although we also acknowledged that it had not provided an efficient solution to the regulation of low-risk wastes. However, as discussed in Section VIII.C of this preamble, since the delisting program was delegated to the EPA Regions on October 10, 1995, a number of innovations have been adopted that have greatly improved the efficiency and effectiveness of the delisting program. EPA will continue these efforts and others in order to keep improving the delisting process.

In addition, as EPA has identified specific mixtures and derived-from wastes which no longer meet the definition of hazardous waste, and has therefore established a number of exclusions in 40 CFR 261.3. Currently, there are over a dozen types of hazardous waste mixtures and residuals excluded or conditionally exempted under section 261.3. See the ''Table of Revisions to 40 CFR 261.3'' in Section VII.C.2 of this notice for a list of these exclusions. This is in addition to other exclusions and conditional exclusions set forth in 40 CFR 261.4 as well in other parts of the hazardous waste regulations.

Furthermore, as discussed in Section VI of this notice, EPA is continuing work to develop exit levels for listed hazardous wastes, so that listed wastes can become ''delisted'' automatically, under a self-implementing procedure. But, as also explained in Section VI of this notice, that is a complex undertaking and, despite best efforts, EPA is not able at this time to propose a technically supported concentration-based exemption.[11] Also, as explained in Section X of this preamble, we are also investigating and will actively pursue other specific exemption proposals.

EPA continues to believe, as it did in 1980, that it would be virtually impossible to try to identify all possible waste mixtures and treated wastes and assess their hazards individually. EPA's rule reasonably retains jurisdiction over both broad classes and places the burden of proof on the regulated community to show that a particular waste has ceased to present a hazard.

Even if all listed hazardous waste mixtures and derivatives could not be

[10] U.S. EPA *Evaluation of Hazardous Waste Delisting Program,* December 2000.

[11] Congressional report language accompanying EPA's FY 2001 appropriations act directs EPA to submit the HWIR model to an independent peer review, and respond publicly to the findings of the peer review prior to using it to establish regulatory determinations. S. Rep. No. 106–410 at 90 (2000)). EPA is currently in the process of preparing for that peer review.

said to meet the statutory hazardous waste definition, at the very least it is reasonable and consistent with RCRA to *presume* that mixtures and derivatives of listed hazardous wastes remain hazardous under the definition, unless that presumption is rebutted through the delisting process. As discussed further in the next section, Congress established clear standards for hazardous waste identification, but did not speak specifically to the issue of the circumstances under which mixtures and derivatives of listed hazardous wastes should be regulated. Under these circumstances, EPA must interpret and implement the statute in a way that effectuates the statutory objectives. The mixture and derived-from rules are the only implementation approach that EPA is aware of at this time that effectuates the protective purposes of RCRA.

(2)(a) Comment: EPA Has Not Met the Requirements Under Section 3001, 42 U.S.C. 6921 and 40 CFR 261.10 and 261.11 for Designating Wastes as Hazardous

These commenters also disagreed with EPA's claim of authority under section 3001 (60 FR at 66348, 64 FR 63390). The commenters believed that EPA had not followed the required procedures or made the findings required by RCRA to identify ''mixture and derived-from wastes'' as hazardous. They noted that sections 3001(a) and (b) outline a two-step process for classifying wastes as hazardous. EPA first must specify criteria to determine if the waste is ''hazardous,'' 42 U.S.C. 6921(a), which is defined as presenting a substantial present or potential hazard to human health or the environment 42 U.S.C. 6904(5). Once the criteria are established—as they have been in 40 CFR 261.10 and 261.11—the commenters stated that EPA must apply these criteria to identify a characteristic of hazardous waste or to list a waste as hazardous. In these commenters' view, the mixture and derived-from rules identify a broad class of wastes as hazardous without regard to the criteria established by EPA. Also, they noted that the proposal did not discuss how mixtures and derived-from wastes pose a substantial present or potential threat to human health or the environment, nor did EPA discuss concentration levels, mobility, persistence, or any other objective factors of hazardousness that are listed in the statute or the regulations.

In addition, numerous commenters from industries, industry associations, utility companies and utility company associations disagreed with EPA identifying mixture and derived-from wastes as a ''class'' under 40 CFR 261.11 (60 FR at 66348, 64 FR at 66390). They believed that such identification required a finding that EPA had reason to believe that individual wastes within the class ''typically or frequently are hazardous'' under the definition at RCRA section 1004(5) (see 40 CFR 261.11(b)). Commenters noted that EPA's own longstanding practice was that, in a class-wide listing determination, ''typically or frequently'' meant that more than 50 percent of the samples taken from that class exhibited some or all of the 40 CFR 261.11(a) criteria (see, *e.g.,* 56 FR 48020, Sept. 23, 1991 and 45 FR 33114, May 19, 1980). The commenters stated that EPA historically has required that samples of a waste class contain concentrations of toxic constituents at 100–1000 times specified health-based numbers to be considered as posing a ''substantial hazard'' under 40 CFR 261.11(a)(3) (see, *e.g.,* 56 FR. 48018, Sept. 23, 1991 and 57 FR 21453, May 20, 1992). They noted that EPA generally requires that wastes typically and frequently contain toxic constituents at ''many times'' health-based levels and that such constituents be mobile and persistent. The current proposal made no reference to these prior practices, nor did it offer evidence that EPA collected or analyzed any samples or otherwise attempted to demonstrate that 50 percent—or any substantial percentage—of mixtures or treatment residues met any of the specific criteria of § 261.11(a). Also, they commented that the proposal offered nothing responsive to the 100–1000 times health-based numbers requirement. In addition, they noted that the class must have ''sufficient uniformity'' to apply the criteria in 40 CFR 261.11 (45 FR 33114). The commenters felt that it was obvious that the class of mixture and derived-from wastes was anything but uniform, a point admitted by EPA (45 FR 33095–96, ''the potential combinations of listed wastes and other wastes are infinite''). Therefore, the class did not have the requisite uniformity needed to be classified as hazardous.

(2)(b) EPA Response

EPA does not agree with comments that the Agency lacks statutory authority under RCRA Section 3001 for either the mixture rule or the derived-from rule. We have the statutory authority to promulgate these rules as part of the authority to ''develop and promulgate criteria for identifying the characteristics of hazardous waste and for listing hazardous waste.'' Among the criteria are the provisions of 40 CFR 261.3, which provide generally applicable criteria for the identification of hazardous waste. The mixture and derived-from rules are included in section 261.3(a)(2), which states that a solid waste is a hazardous waste if ''[i]t meets any of the following criteria.'' These rules ensure that listed hazardous wastes that are mixed with other wastes or treated in some fashion do not escape regulation as hazardous waste until EPA has made some determination that they no longer threaten human health or the environment. This section also includes the exclusions from the definition of hazardous waste, including those promulgated today, where EPA has made specific findings on the record that the excluded wastes are no longer hazardous under the criteria set forth in the exclusions. We will continue to pursue additional approaches to exempt low-risk wastes, as appropriate.

The commenters' position rests largely on the assumption that mixtures and derivatives of wastes are entirely new and distinct substances from the originally listed waste, leading to the apparent conclusion that EPA must make a separate, record-based finding of hazardousness for each of the infinite variations of mixtures and derivatives generated from the wastes EPA has listed. EPA disagrees. In upholding the ''contained-in policy,'' the U.S. Court of Appeals for the D.C. Circuit deferred to EPA's conclusion that a listed hazardous waste cannot be presumed to change character when it is mixed with an environmental medium. *Chemical Waste Management* v. *EPA,* 869 F.2d 1526, 1539 (1989). We believe that the same reasoning applies to the mixture rule. Similarly, as discussed in Section VII.A.2, waste management residuals can contain constituents from the originally listed waste at even higher concentrations than the original waste and, therefore, may pose a hazard. Indeed, EPA views the mixture and derived-from rules as applications of the general principle that ''a hazardous waste will remain a hazardous waste'' unless it is excluded through a regulatory process. 40 CFR 261.3(c)(1). *See Chemical Waste Management,* 869 F.2d at 1539 (upholding contained-in policy as interpretation of § 261.3(c)(1)).

EPA's approach is consistent with Congress' intention that hazardous waste be regulated for the long term under a comprehensive regulatory program. One of the findings upon which the 1976 RCRA legislation was based was that ''hazardous waste presents, in addition to the problems associated with nonhazardous solid waste, special dangers to health and requires a greater degree of regulation than does nonhazardous solid waste.''

Public Law No. 94–580, section 1002(5). With enactment of the Hazardous and Solid Waste Amendments (HSWA) in 1984, Public Law No. 98–616, Congress strengthened that provision and added three more findings: ''the placement of inadequate controls on hazardous waste management will result in substantial risks to human health and the environment; if hazardous waste management is improperly performed in the first instance, corrective action is likely to be expensive, complex , and time consuming; certain classes of land disposal facilities are not capable of assuring long-term containment of certain hazardous wastes * * *''. RCRA section 1002(b)(5), (6), (7). Similarly, when RCRA was enacted in 1976, Congress stated one of the objectives of the Act was ''regulating the treatment, storage, transportation, and disposal of hazardous wastes which have adverse effects on health and the environment.'' Public Law No. 94–580, 1003(a)(4). This provision too was replaced with a stronger statement by HSWA, that an object of the statute is ''*assuring* that hazardous waste management practices are conducted in a manner which protects human health and the environment.'' (Emphasis added.) RCRA 1003(a)(4). Further, HSWA added as national policy that hazardous waste ''should be treated, stored, or disposed of so as to minimize the present and future threat to human health and the environment.'' RCRA 1003(b). It is clear that Congress' principal objective under Subtitle C was protecting against threats to human health and the environment caused by hazardous waste. We acknowledge that such a goal does not imply that all mixtures and derived-from wastes must be regulated under full Subtitle C requirements, regardless of the potential risks they pose, but we believe that it is reasonable to regulate these wastes until it is shown that such wastes do not pose a hazard.

The D.C. Circuit Court of Appeals has characterized RCRA as establishing ''a ''cradle-to-grave'' regulatory structure overseeing the safe treatment, storage and disposal of hazardous waste.'' *United Technologies Corp.* v. *EPA,* 821 F.2d 714, 716 (D.C. Cir. 1987). The mixture and derived-from rules are a necessary part of this approach, by maintaining jurisdiction over mixtures and derivatives of already listed waste. Without these rules, as explained in Section VII.A.(2), the ''cradle-to-grave'' structure would have a major loophole, undermining the objectives of RCRA.

The delisting provision supports the mixture and derived-from rules as a means to address wastes that could pose unacceptable risks. In amending RCRA section 3001 in 1984, Congress enacted subsection (f) to require the Agency to ''consider factors (including additional constituents) other than those for which the waste was listed'' if the Agency ''has a reasonable basis to believe that such additional factors could cause the waste to be a hazardous waste.'' The legislative history shows that Congress was concerned that both as generated wastes and wastes resulting from treatment were exiting the Subtitle C system while still hazardous. ''The delisting process allows petitioners (usually individual hazardous waste generators or treatment facilities) the opportunity of showing that their wastes are significantly different—because of treatment, or because they are generated in a different process—from listed wastes of the same type. * * * Under this amendment, there would no longer be a risk that delisting a waste means releasing waste which may still be hazardous from regulation.'' H.R. Rep. No. 98–198 Part I (May 17, 1983). Congress made this change because it believed that under its previously existing delisting regulations, EPA allowed wastes that remained hazardous to exit the Subtitle C system. S. Rep. No. 98–284 (Oct. 28, 1983). The language and legislative history reflect Congress' assumption that treatment derivatives from listed wastes *would* remain subject to Subtitle C absent a delisting.

The land disposal restrictions (LDR) provisions of the statute further demonstrate that the mixture and derived-from rules are consistent with Congress' intent. The statute authorizes EPA to promulgate regulations establishing levels or methods of treatment, ''if any,'' that substantially diminish the toxicity or mobility of the hazardous waste, and provide that the waste may thereafter be disposed of in a land disposal facility that ''meets the requirements of [Subtitle C].'' RCRA section 3004(m). This section demonstrates two things. (1) Congress contemplated the possibility that there may be hazardous wastes for which no form of treatment would be adequate; and (2) Congress assumed that waste that was treated according to the promulgated treatment standards would nonetheless still be disposed of in a Subtitle C (hazardous waste) facility. This provision is at odds with the commenters' assertion that, once treated, a hazardous waste becomes a fundamentally different waste and is unregulated unless EPA undertakes a separate rulemaking to list the treated waste.

Other provisions of the 1984 amendments to RCRA relating to land disposal provide further support for the mixture and derived-from rules. See, e.g., section 3004(o) (establishing minimum technological requirements for land-based hazardous waste management units); section 3004(p) (establishing groundwater monitoring requirements); section 3005(c)(3) (requiring 5-year permit reviews for land disposal facilities); section 3005(e)(2), (3) (establishing interim status termination dates for certain non-compliant land disposal facilities); section 3005(i), (j) (establishing specific additional requirements for certain land-based units); section 1002(b)(7) (finding that certain classes of land disposal facilities are not capable of assuring long-term containment). Some commenters suggest that treatment residuals from listed hazardous wastes do not remain hazardous. We believe it is unlikely Congress would have created such stringent requirements for land disposal, if it intended for treatment residuals to escape Subtitle C regulation.

Taken to the extreme, the view that mixtures containing listed wastes should not be regulated as hazardous wastes would imply that most listed hazardous wastes, even if they reached a management unit in ''pure'' form, would cease to be hazardous once they entered the unit, since most units contain mixtures of different wastes. However, the RCRA statute clearly assumes that units would not only receive, but continue to contain, hazardous waste. See, e.g. section 3005(j)(11) and (12)(A), Moreover, the comprehensive requirements mandated for hazardous waste management units, including the technical standards of section 3004 and the permitting regime of section 3005, could be undermined if facilities receiving listed hazardous wastes could argue that their management units are subject to this scheme only as long as they are receiving the waste, but that they become exempt thereafter since the units do not contain hazardous waste.

Various provisions in RCRA appear to contemplate that at least some hazardous waste mixtures and derivatives would themselves be hazardous. See, e.g., section 3004(d)(2)(A), (B) (addressing liquid hazardous wastes, ''including free liquids associated with any solid or sludge,'' suggesting that liquid derivatives of hazardous waste would themselves be hazardous). Another example is the language in section 3005(b), which requires permit applicants to provide information regarding hazardous wastes and ''combinations of * * * hazardous waste and any other solid waste'' to be

managed at the permitted facility, as well as information regarding the site at which the ''products of treatment'' of hazardous waste will be managed.

Finally, the appropriations act provision that EPA is implementing with today's rule requires that the mixture and derived-from rules would continue in effect while EPA developed revisions to the regulations. Public Law No. 102–389, 106 Stat. 1571 (October 1992). That provision instructed EPA to ''promulgate revisions to paragraphs (a)(2)(iv) and (c)(2)(i) of 40 CFR 261.3, as reissued on March 3, 1992 * * *''. Congress expressed no intent that these rules be rescinded or replaced.

We also disagree with commenters' assertion that the mixture and derived-from rules violate the ''two-step process'' of section 3001(a) and (b) for hazardous waste identification. It is true that the statute requires EPA to promulgate criteria for hazardous waste identification (section 3001(a)) and, based on those criteria, to identify characteristics of hazardous waste and to list hazardous wastes (section 3001(b)). In general, EPA has done this in separate steps. *See* 40 CFR part 261, Subpart B (criteria) and Subparts C and D (characteristics and lists). However, the statute does not preclude EPA from creating self-implementing criteria, as EPA has done with the mixture and derived-from rules. EPA does not interpret 3001(b) as imposing an obligation on EPA to undertake a separate waste identification rulemaking step following the development of self-implementing criteria. Alternatively, the mixture and derived-from rules could be viewed as a simultaneous exercise of EPA's 3001(a) and 3001(b) authority. Nothing in the statute prevents EPA from simultaneously, in combined regulations, establishing the criteria for waste identification, and identifying the characteristics of hazardous waste and listing waste.

We agree with commenters who point out that EPA has not used the class listing process under 40 CFR 261.11(b) to list mixtures and derived-from wastes as a class. However EPA does not agree that mixtures and derivatives must be individually listed or identified as hazardous wastes before being subject to Subtitle C jurisdiction. As previously stated, mixtures and derivatives are identified as hazardous waste by virtue of containing or coming from wastes that have been listed pursuant to the criteria in 40 CFR 261.11. EPA cannot presume that the hazardous constituents that are the basis of the original listing are always eliminated or rendered nontoxic simply because a waste is mixed with other wastes or managed in some fashion.

(3)(a) Comment: EPA Has No Authority Under Sections 3002–3004 of RCRA To Designate Wastes as Hazardous

Several commenters from industries, industry associations, utility companies, utility company associations and waste management companies also disagreed with EPA's claim of authority under sections 3002–3004 of RCRA. They argued that these sections of RCRA provide for hazardous waste management standards for generators, transporters, and treatment, storage and disposal facilities, not for identifying hazardous wastes. Instead, that role is unambiguously carried out by section 3001. 42 U.S.C. 6921, and in previous promulgations and in litigation, EPA relied primarily on section 3001 to justify the mixture and derived-from rules.

(3)(b) EPA Response

In citing sections 3002–3004 in the discussion of EPA's statutory authority, we did not intend to imply that these sections by themselves provide statutory authority for the mixture and derived-from rules. Rather, our intent was to explain that these sections inform the process of identifying hazardous waste under section 3001 because the purpose of identifying a solid waste as hazardous is to ensure that it is managed properly.

The statute directs EPA to regulate hazardous waste generators (section 3002(a)), hazardous waste transporters (section 3003(a)), and hazardous waste treatment, storage, and disposal facilities (section 3004(a)) ''as necessary to protect human health and the environment.'' It is our view that this informs the decision of when waste should be identified as hazardous and therefore subject to the regulatory requirements of Subtitle C . In deciding whether to identify a waste as hazardous under section 3001, EPA considers whether Subtitle C controls on the waste are necessary to protect human health and the environment. We have therefore consistently interpreted section 3001 to give us broad flexibility in fashioning criteria for hazardous wastes to enter or exit the Subtitle C regulatory system. See, *Military Toxics Project* v. *EPA,* 146 F.3d 948, 958 (D.C. Cir. 1998). As discussed above, this interpretation is consistent with the statutory purpose of protecting human health and environment by establishing a comprehensive hazardous waste regulatory program. (RCRA sections 1002, 1003).

In addition to providing the context in which the determination of whether a waste ''should be subject to the requirements of Subtitle C,'' sections 3002–3004 allow us to continue to impose requirements on waste handlers until wastes have ''cease[d] to pose a hazard to the public.'' *Shell Oil Co.* v. *EPA,* 959 F.2d 741, 754 (D.C. Cir. 1991). See also *Chemical Manufacturers Assoc.* v. *EPA,* 919 F.2d 158, 162–65 (D.C. Cir. 1990) (EPA may regulate the disposal of nonhazardous wastes in a hazardous waste impoundment under section 3004) and *Chemical Waste Management, Inc.* v. *EPA,* 976 F.2d 2, 8, 13–14 (D.C. Cir. 1992) (EPA may require further treatment of wastes under section 3004 even though they cease to exhibit a hazardous characteristic). Without the mixture and derived-from rules, EPA could not effectively carry out its obligation under sections 3002–3004 to protect human health and the environment. Thus, in addition to the specific authority of section 3001, the mixture and derived-from rules are authorized under section 2002(a)(1), which empowers the Administrator to ''prescribe * * * such regulations as are necessary to carry out his functions'' under RCRA.

C. Regulatory Cost of the Mixture and Derived-From Rules

(1) Summary of Comments on the Regulatory Cost of the Mixture and Derived-From Rules

EPA received comments from five commenters in response to both the 1995 and the 1999 HWIR proposals concerning the regulatory cost of the mixture and derived-from rules. Of those comments, four were received from industries, and one was from an industry association. The commenters generally argued that the rules constituted over-regulation of low-risk wastes causing high costs and heavy burdens with little benefit to human health and the environment. A summary of the specific issues raised by commenters is provided below.

One industry commenter argued that the rules have added significant costs to the operation of manufacturing facilities throughout the nation, while providing insignificant benefits to human health and the environment. The commenter noted that the generation of large quantities of hazardous wastewaters based solely on the practice of efficient, centralized wastewater treatment has led the company to evaluate the segregation of hazardous and non-hazardous wastewaters, to prevent the attachment of a ''hazardous'' label to those non-hazardous wastewaters. Such a segregation would require a second treatment facility and much re-piping,

with the net result that millions of dollars would be expended and there would be no improvement in the wastewaters ultimately discharged to the environment through two, rather than one, discharge points. All that would be achieved is an apparent reduction in hazardous waste generation which does not, in reality, represent a decrease in waste generation, treatment or discharge, but rather a reporting game and artificial waste minimization driven by EPA requirements. It is this kind of ''game'' that compromises the credibility of both EPA and the regulated community and imposes a significant burden on the regulated community.

Another industry commenter noted that managing the residuals as if they were listed hazardous waste was significantly more expensive than managing the waste in accordance with solid waste regulations. For example, in 1995 transportation and disposal of ash from a hazardous solids incinerator cost approximately $185,000. In comparison, the ash could be managed in a state permitted Subtitle D landfill as non-hazardous waste for about $25,000. Another industry stated that these rules have resulted in significant expense that has diverted resources away from greater environmental opportunities.

One association commenter stated that the rules frequently cause waste codes to be carried through and applied to wastes that are fundamentally different from the original waste considered in the development of the listing classification. The commenter noted that there are many instances in which the risk associated with the original listed waste simply does not carry through in the same way, and that the composition and nature of any risk posed by these materials often bears little or no relationship to the original listed waste. Specific examples cited include (1) Wastewaters where most of the arsenic has been precipitated and removed, (2) debris from hazardous waste refractories undergoing repair, and (3) wastewaters that had received ethylene oxide as part of an emergency incident. The costs and impacts of this automatic waste-code carry-through are quite significant. Much of the industry operates through smaller ''batch'' processes, while the regulations are crafted for a continuous manufacturing process. And, in many operations, delisting the mixture is not an option, as the facility can only store the mixture on-site for 90 days, which is not enough time for a delisting.

An industry association also stated that the costs imposed by the rules from a number of member companies are easy to identify: on-site storage costs, paperwork and administrative costs, higher shipping and transportation costs, and higher treatment, storage and disposal costs. And, these are the same types of costs analyzed and tallied by EPA in documenting the cost savings it attributes to the modified exemption for hazardous wastes listed solely for a characteristic of ignitability, corrosivity and/or reactivity. The commenter also stated that another significant cost of the current regulatory regime was the extra time and effort required to evaluate and apply the rules in the real world. Even after 20 years, facilities still have difficulty evaluating when, whether and why certain waste streams must be managed as Subtitle C hazardous wastes under this approach.

2. Response to Comments on Regulatory Cost of the Mixture and Derived-From Rules

We agree that the mixture and derived-from rules have captured wastes that could safely be managed outside of RCRA Subtitle C regulation. As explained below, we have addressed specific cases of such over-regulation through targeted rulemaking in the past, and we will continue to explore options for exempting wastes that do not warrant Subtitle C regulation. However, we do not agree that hazardous waste regulation of mixture and derived-from waste provides no additional protection of human health and the environment. For example, as we discuss in Section VII.A, wastewaters prior to discharge may contain constituents at levels that could pose unacceptable risks if they are mismanaged. Furthermore, the mixture and derived-from rules address cross-media transfer of persistent hazardous chemicals from the wastewater to the treatment sludge.

One way of reducing the regulatory burden available to individual waste generators is the delisting process. Generators have the option of petitioning the Agency under 40 CFR 260.20 and 40 CFR 260.22 to exclude their wastes from the lists of hazardous wastes in subpart D of part 261 if they believe those wastes no longer pose risk to human health and the environment. Since the delisting program was delegated to the EPA Regions on October 10, 1995, a number of innovations have been adopted that have greatly improved the efficiency and effectiveness of the delisting program. In particular, EPA Region VI's award-winning program has created a process that produces a decision within an average of 180 days, provides a streamlined application checklist, proactively coordinates with State personnel, and includes a user-friendly, stand-alone software program that produces an updated, state-of-the art assessment of risks associated with delisting a petitioned waste. In addition, EPA and the applicant now work together to develop an initial application that can be approved without the need for major revisions, which is a major factor in reducing the processing time. EPA will continue these efforts and others in order to keep improving the delisting process. Since 1980, EPA has excluded an estimated 45 million tons of waste, resulting in an estimated cumulative cost savings between $1.1 billion and $1.3 billion (in 1999 dollars). In 2000 alone, we estimate cost savings of approximately $105.4 million.[12]

In addition, EPA has taken steps since the mixture and derived-from rules were promulgated in 1980 to further reduce the scope, and therefore the cost, of these rules when appropriate. As one commenter to the 1999 proposal pointed out, eighteen months after the original mixture and derived from rules, EPA promulgated the first of several exclusions for low-risk waste from the definition of hazardous waste. Over the past twenty years, EPA has developed exclusions and/or tailored regulations to reduce the regulatory cost for more than a dozen types of hazardous waste mixtures and residuals. (see table below)

[12] U.S. EPA *Evaluation of Hazardous Waste Delisting Program,* December 2000.

REVISIONS TO 40 CFR 261.3 THAT HAVE REDUCED THE REGULATORY COST OF THE MIXTURE AND DERIVED-FROM RULES

CFR citation	Hazardous waste(s) affected	Year promulgated (FR citation)
40 CFR 261.3(a)(2)(iv)(A) and (B)	Certain solvents managed in wastewater treatment systems.	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(C)	Certain petroleum wastes discharged to the refinery oil recovery sewer.	1981 (46 FR 56582) Additional wastes added in 1998 (63 FR 42184)
40 CFR 261.3(a)(2)(iv)(D)	De minimis losses of commercial chemical product.	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(E)	Certain laboratory wastewaters	1981 (46 FR 56582)
40 CFR 261.3(a)(2)(iv)(F) and (G)	Certain carbamate wastewaters	1995 (60 FR 7848)
40 CFR 261.3(a)(2)(v)	Used oil	1992 (57 FR 41611)
40 CFR 261.3(c)(2)(ii)(A)	Certain waste pickle liquor sludges	1984 (49 FR 23284)
40 CFR 261.39(c)(2)(ii)(B)	Wastes derived from burning certain oil-bearing wastes as fuel.	1987 (52 FR 11819)
40 CFR 261.3(c)(2)(ii)(C)	Wastes derived from high temperature metals recovery of certain hazardous wastes.	1992 (57 FR 37263)
40 CFR 261.3(c)(2)(ii)(D)	Certain types of biological treatment sludge	1995 (60 FR 7848)
40 CFR 261.3(c)(2)(ii)(E)	Certain types of catalyst inert support media	1998 (63 FR 42184)
40 CFR 261.3(f)	Certain types of debris contaminated with a hazardous waste.	1992 (57 FR 37264)

In each of these revisions to 40 CFR 261.3, EPA considered the case-specific circumstances of the waste affected and, through the formal rulemaking process, determined that these wastes merited special consideration under the hazardous waste identification rules. In many cases, these wastes still warranted enough concern to impose specific management and other implementation requirements. For example, the solvent exclusions in 40 CFR 261.3(a)(2)(iv)(A) and (B) require that (1) these wastes are managed in a system the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act, and (2) the total weekly usage of these solvents divided by the average weekly flow of the wastewater into the treatment works would not exceed a specific regulatory level (either 1 ppm or 25 ppm).

Under today's final rule, EPA has continued the effort to reduce the burden from the mixture and derived-from rules where appropriate by excluding wastes listed solely for ignitability, corrosivity, and/or reactivity, once the waste no longer exhibits any of the hazardous waste characteristics (40 CFR 261.3(g)). We are also finalizing a conditional exemption for mixed waste from the mixture and derived-from rules, provided the mixed waste is handled in accordance with 40 CFR part 266, Subpart N. (40 CFR 261.3(h))

Finally, over the past twenty years EPA has promulgated numerous rules establishing exclusions or conditional exemptions from the solid and hazardous waste definitions, and from regulatory requirements for particular wastes and management practices. These exemptions are part of EPA's overall effort to avoid unnecessary regulation of waste.

EPA plans to continue work on other types of hazardous waste exemptions, including the additional targeted exemptions for certain categories of wastes and management practices, and the concentration-based exemptions (HWIR exemption) discussed in the November 19, 1999 proposal. We also plan to continue on-going efforts to streamline the existing delisting program.

In regard to the specific examples of over-regulation claimed by one commenter (see comment # WH2P–00035, page 10), it is difficult for EPA to fully evaluate these cases without more specific data. For example, in the case of wastewaters where most of the arsenic has been precipitated and removed, it is not clear whether there are any other hazardous constituents of concern in the treatment sludge, and whether the residual arsenic might still pose a risk (depending on waste volume and management method). In the case of contaminated bricks from hazardous waste refractories undergoing repair, it would appear that the exclusion for debris [40 CFR 261.3(f)] could address this concern. Finally, for wastewaters that had received ethylene oxide as part of an emergency incident, while it is true that ethylene oxide eventually breaks down to ethylene glycol, this reaction is not instantaneous. When released into water, ethylene oxide will primarily be lost by three processes: volatilization, hydrolysis and biodegradation. The half-lives of these reactions range from a few hours to up to 20 days.[13] Ethylene oxide itself is toxic, and if these wastewaters were automatically considered non-hazardous, they could present a substantial risk, depending on actual concentrations and exposure patterns. Both low level chronic exposure and acute high levels of ethylene oxide can lead to a broad spectrum of neurological effects. Also, inhalation studies have shown that exposure to ethylene oxide can result in a wide range of carcinogenic effects, and NIOSH considers ethylene oxide to be a potential occupational carcinogen.[14] Therefore, EPA does not agree that such a mixture should be automatically excluded from hazardous waste regulation. More importantly, since the purpose of this rulemaking is not to evaluate individual wastestreams, EPA does not believe this example demonstrates that the mixture and derived-from rules themselves are unnecessary as a general matter.

EPA understands that the RCRA regulations, in particular the waste identification regulations, can be difficult to understand. We have attempted to use plain language in drafting today's revised regulatory language, and will continue to make regulatory language more accessible to readers in the future. In addition, we believe that the mixture and derived-from rules are more straightforward than the alternative of having to evaluate each combination and permutation of

[13] Agency for Toxic Substances and Disease Registry. (1990). Draft Toxicological Profile for Ethylene Oxide.

[14] National Institute for Occupational Safety and Health. (1989). Ethylene Oxide Sterilizers in Health Care Facilities, Engineering Controls and Work Place Practices. DHHS (NIOSH) No. 89–115.

listed waste on a case-by-case basis. We believe this alternative would create uncertainty for the regulated community, state agencies, the public, and the courts, as various stakeholders press conflicting views as to whether a particular waste does or does not continue to meet the listing description.

VIII. What Were the Major Comments on the Revision to 40 CFR 261.3 To Exclude Wastes Listed Solely for Ignitability, Corrosivity, and/or Reactivity, and How Has EPA Responded to Them?

Most commenters generally supported revisions to 40 CFR 261.3 to various degrees. Chemical-producing industries as well as Federal government agencies who commented were unanimous in support. Most states supported the proposed revisions to the rules to varying degrees. Below are summaries of the major comment issue areas for this proposed exclusion. For more detailed comment responses, please see *Hazardous Waste Identification Rule: Revisions to the Mixture and Derived-From Rules Response to Comments Document.*

A. Eligibility of Waste Listed for the Toxicity Characteristic

(1) Comments on Eligibility of Waste Listed for the Toxicity Characteristic

EPA received comments from 12 commenters in response to both the 1995 and the 1999 proposals concerning inclusion of wastes listed solely for the toxicity characteristic in the expanded exclusion. Of those comments, four were received from industry, two were from industry associations, four were from utility companies or utility company associations, one was from a Federal Government Agency, and one was from an industry consultant. A summary of the specific issues raised by commenters is provided below.

While supporting the proposed exclusion, these commenters urged EPA to modify the proposal so the exclusion would apply to wastes listed due to any of the four characteristics, including the toxicity characteristic. Commenters asserted that it was not logical to limit the exclusion for derived-from wastes to three of the four characteristics, regardless of the fact that no listed wastes are listed solely on the basis of the toxicity characteristic. One commenter stated that it appears as if EPA suspects that wastes containing TC constituents below the toxicity characteristic are not really safe. A few commenters noted that in the future, wastes that may be listed solely for the toxicity characteristic should be eligible for the exclusion. Another commenter also noted that the proposed regulatory language does not provide for any additional hazardous waste characteristics that might be promulgated in the future. Commenters suggested that EPA replace references to ignitability, corrosivity, and reactivity in the proposed regulatory language for 40 CFR 261.3(g) with references to any characteristic of hazardous waste identified in subpart C, reflecting the approach and language used in the current mixture rule.

Several commenters noted that EPA did not offer an explanation for omitting wastes listed solely because they exhibit the characteristic of toxicity from eligibility for the proposed exclusions that would be granted by 40 CFR 261.3(g). EPA did explain that, since no listings to date have been based on the toxicity characteristic, EPA was proposing to limit the new revision to the derived-from rule to wastes listed because they exhibit only the characteristics of ignitability, corrosivity, or reactivity. However, the commenters believed it is confusing to give no explanation for proposing the elimination of an existing exclusion from the mixture rule, even if no wastes now exist that are eligible for the exclusion. Therefore, the commenters recommended that the preamble for the final rule contain such an explanation.

(2) EPA Response to Comments on the Eligibility of Waste Listed for the Toxicity Characteristic

EPA does not agree that wastes listed solely for the toxicity characteristic (TC) should be eligible for the exclusion. As we discussed in the 1995 HWIR proposal, wastes may still pose some risk concerns even when TC constituents are present below TC levels (60 FR 66369, December 21, 1995).

The hazards that the TC regulation addresses, carcinogenicity and chronic chemical toxicity via contaminated groundwater/drinking water, have fewer clear thresholds than the other characteristics. Wastes that exhibit the characteristics of ignitability, corrosivity or reactivity typically pose acute hazards which can be addressed by application of appropriate treatment to decharacterize the waste. For example, ignitable liquid waste or waste chemical oxidizers can be treated by combustion, and the ash treatment residue poses no ignitability threat to landfills. Similarly, strong acid or basic wastes, if effectively neutralized, generate residues that pose no threat of skin damage. Waste explosives or highly reactive chemicals that are denatured or reacted-out under controlled conditions also generate residues that pose no explosion or reaction threat.

The TC chemicals have less clear thresholds below which they pose little or no hazard for several reasons. Toxic chemicals pose a risk that is typically dependent on a range of factors, and assessment of hazard from toxicity is much more complex, and involves many more variables, than assessment of hazard from the other three characteristics. A waste that does not exhibit the toxicity characteristic for a particular chemical may nonetheless pose a substantial hazard depending on such factors as the volume of the waste, the exposure route being assessed, and the amount of dilution and attenuation that is assumed prior to exposure. These factors, along with others, are taken into account in making hazardous waste listing determinations based on toxicity. See 40 CFR 261.11((a)(3). In addition, as persistent chemicals move through the environment, they can accumulate, posing long-term chronic risks even at levels below those set for the toxicity characteristic. Thus, the toxicity characteristic is not designed to capture all of the wastes that might present a substantial hazard for the TC constituents. Rather, the TC is designed to capture wastes that may pose a substantial hazard, without the need to conduct a waste-specific risk assessment. In fact, when EPA promulgated the TC regulation, we stated that the regulation is intended to identify ''* * * broad classes of wastes which are clearly hazardous * * *''. We also noted that ''wastes that do not exhibit the hazardous waste characteristics are not necessarily non-hazardous.'' (55 FR 11799, March 29, 1990). In identifying TC hazardous wastes as ''clearly hazardous'' the agency was identifying a universe of wastes that it believed may pose high enough risk so as to *always* require classification as hazardous. In noting that non-TC wastes are not necessarily non-hazardous, the agency both recognized the non-threshold (i.e., continuous) nature of TC constituent risks, and recognized that wastes falling just below the TC values may pose risks that are just below a ''clearly hazardous'' designation, and which may sometimes warrant classification as hazardous. EPA has in fact listed wastes based on toxicity where the waste did not fail the TCLP for the constituent of concern. (see, for example, the final petroleum waste listing, 63 FR 42154 (August 6, 1998)).

EPA's decision to not exclude wastes listed solely for the TC could potentially affect the regulation of certain inorganic wastes that EPA has recently proposed

to list as hazardous. (65 FR 55684, September 14, 2000). The issue had been purely theoretical before that point because no waste had ever been listed for the TC. In the inorganics listing determination proposal, however, EPA proposed to list baghouse filters from antimony oxide production for the TC. Despite the fact these wastes fail the TC for lead and arsenic, they are not always being managed as Subtitle C hazardous waste, nor are these wastes always treated to the appropriate LDR standards. By listing them, we would clarify their regulatory status. In the preamble to the inorganics listing proposal, EPA noted that proposed revisions to the mixture and derived-from rules did not include an exclusion for wastes listed for the TC (65 FR 55705). EPA did not receive any public comments in response to this discussion in the Inorganics Listing proposal.

B. Toxicity of Wastes Listed for Ignitability, Corrosivity, and/or Reactivity

(1) Comments on Toxicity of Wastes Listed for Ignitability, Corrosivity, and/or Reactivity

EPA received two comments in response to the 1999 proposal concerning the potential toxicity of waste under the proposed expanded exclusion to the mixture and derived-from rules. One was from a waste management association and one from a State agency. A summary of the specific issues raised by commenters is provided below.

The commenters believed that EPA must evaluate the properties carefully, especially the toxicity, of the 29 compounds proposed to be excluded. They assert that some of these wastes are acutely hazardous and merit a thorough review to ensure that the exclusion is appropriate. The waste management association noted that EPA had not performed an evaluation of the negative environmental impact associated with eliminating these codes. Ignitable, corrosive, and reactive wastes could contain substantial levels of toxic constituents that could be low enough not to exhibit a characteristic of ignitability, corrosivity or reactivity, yet high enough to cause environmental damage. One damage case or Superfund site can cause damages far in excess of the $4.6 million estimated savings predicted by EPA. The waste management association further argued that EPA's Hazardous Waste Characteristics Scoping Study (Nov. 15, 1996) identified numerous gaps in the current RCRA identification of characteristic wastes. The commenter believed that gaps were so serious that EPA should not be proposing to eliminate any listing that was based on a characteristic until the deficiencies identified in the 1996 Scoping Study were addressed fully. Also, EPA must not eliminate any listing once the characteristic is removed, because the underlying hazardous constituent still represents a substantial threat even after LDR treatment.

(2) EPA Response to Comments on Toxicity of Wastes Listed for Ignitability, Corrosivity, and/or Reactivity

EPA continues to believe that wastes that were listed only for the characteristics of ignitability, corrosivity, and reactivity should become excluded once they no longer exhibit any characteristic, including the toxicity characteristic. While it is true that these wastes could contain constituents that were not considered in the original listing determination, EPA does not believe this possibility, without information demonstrating some particularized basis for concern, warrants continued regulation of the waste under Subtitle C once it is decharacterized. This is because of the unique nature of listings based on the three characteristics in question. (See the discussion, in Section VIII.A. above, regarding the differences between wastes listed for the toxicity characteristic and wastes listed for the characteristics of ignitability, corrosivity and reactivity). These listings are unlike toxicity-based listings, which involve development of detailed risk assessments and consideration of a range of technical factors. See 40 CFR 261.11(a)(3). In contrast, the basis for listings based on one of these characteristics is simply that the waste exhibits the relevant characteristic (see 40 CFR 261.11(a)(1)).

Listings that are based on 40 CFR 261.11(a) criteria increase the clarity and certainty of the applicability of the Subtitle C system to these wastes. By listing the waste, EPA clarifies that it is hazardous without the need for a site-by-site demonstration that the waste in fact exhibits the characteristic, thereby simplifying implementation and enforcement regarding these wastes. EPA does not believe these listings should alter the basic principle that a characteristic waste should not be regulated as hazardous if it no longer exhibits the characteristic. Consistent with this approach, EPA provided in 1981 an exemption from the mixture rule for wastes listed for one of these characteristics that no longer exhibits the characteristic (see 46 FR 56582, November 17, 1981). Today's rule provides a conforming change to the derived-from rule, which, because the 1981 rule only focused on mixtures, does not currently contain a comparable exemption. (see 60 FR 66349, December 21, 1995). The same rationale also supports the inclusion of as-generated waste in today's rule (although, since these wastes were listed solely on the basis of exhibiting a characteristic, EPA expects these wastes to exhibit the characteristic at the point of generation). Thus, EPA does not believe that the possibility that these wastes may contain additional hazardous constituents not considered in the original listing justifies continued regulation of the waste.

As stated earlier, EPA already excludes mixtures of these kinds of wastes, once the basis for listing these wastes has been removed. In addition, unlisted characteristic waste becomes non-hazardous when it ceases to be characteristic. Expanding the exclusion to non-mixtures that similarly do not exhibit the characteristic (particularly treatment residuals) would still be protective of human health and the environment. If there is any information that indicates that the original listing determination should have been based on toxicity risks, then the proper remedy is to amend the basis for listing the waste . The public can petition EPA to reconsider the basis for listing any such waste .

In regard to the toxicity of the listed chemicals themselves, EPA has examined the most recent toxicity data in IRIS concerning the chemicals in the 29 wastes listed solely for a characteristic, and does not believe these chemicals present a particular basis for concern. We found that fourteen of the chemicals have RfD's or RfC's available in IRIS. (This includes the eight F003 solvents discussed below—see Section VIII.C. of the preamble). EPA used these RfCs and RfDs to calculate conservative screening-level health-based numbers (HBN) for those chemicals, and compared them to the relevant Universal Treatment Standards (UTS) these chemicals would need to meet under Land Disposal Restrictions, in those cases in which numerical standards were available. For most of those chemicals, the relevant UTS standards are much *lower* than the conservative health-based numbers calculated for water and soil ingestion pathways. As discussed in Section VIII.C below, the level for one of the chemicals, n-butyl alcohol, is not significantly higher. Therefore EPA believes that excluding wastes that have

been listed solely for a characteristic of ignitability, corrosivity, or reactivity, when they have been decharacterized (i.e., exhibit none of the four hazardous waste characteristics), is protective of human health and the environment. However, in the future, if additional information becomes available, we may decide to reconsider the basis of listing for one or more of these wastes.

C. Eligibility of F003 Solvents for This Exclusion

(1) Comments on Eligibility of F003 Solvents for This Exclusion

EPA received comments from 17 commenters in response to the 1995 and 1999 proposals concerning the inclusion of F003 solvents in the expanded exclusion to the mixture and derived-from rules. Of those comments, five were from State Agencies, three were from utility companies or associations, four were from industries, two were from Federal Agencies, two were from waste management associations, and one was from an industry association. A summary of the specific issues raised by commenters is provided below.

About two-thirds of the commenters supported including F003 wastes in the proposed exclusion. However, one industry noted that this proposed revision would have little effect beyond eliminating the derived-from rule for a small number of wastes. Many commenters noted that if the solvent contained, before use, one or more of the toxic solvents specifically listed in F001, F002, F004, or F005, at 10 percent or more by volume, it would be regulated as that waste code. Therefore a blanket exclusion for all categories of F003 is appropriate because toxics, when present, will be addressed under other applicable waste codes. One State and two Federal commenters stated that any toxic solvents contained in an F003 spent solvent blend would not escape proper treatment because of the land disposal restrictions (LDR) program. They also noted that solvent mixtures/blends meeting the F003 listing description and containing a certain percentage of toxic solvents also will carry the waste code F001, F002, F004 and/or F005 and therefore, be subject to treatment requirements under the LDR program.

Four commenters did not support including F003 in the proposed exclusion. They argued that the listing description for F003 contains a reference to other solvent wastes (F001, F002, F004, or F005) that are listed for toxicity. Therefore, ignitability was not the only characteristic of concern. In addition, certain F003 solvents themselves may also be toxic, upon consideration of new data developed since 1985. Specifically, the commenter cited a National Toxicology Program, National Institutes of Environmental Health Sciences, Management Statistics Report dated January, 1999 on the carcinogenicity of ethylbenzene (an F003 waste).

In addition, one State noted that in the April 30, 1992 proposal to revise the Hazardous Waste Identification Rule, EPA was considering a separate rulemaking to modify the basis for listing F003 and other wastes listed solely for a characteristic because of concerns about toxicity and/or carcinogenicity. If the chemicals in these wastes are either toxic or carcinogenic according to EPA's own determinations, they should be identified as such in 40 CFR part 261, subpart D.

Commenters also argued that F003 wastes ''often'' contain toxic constituents other than the solvents themselves. One commenter noted that EPA states in 50 FR 53317 (December 31, 1985) ''In fact, solvents become spent when they have become contaminated with other materials, (i.e., heavy metals or toxic organic compounds) and must be disposed, reprocessed or reclaimed.'' EPA further states '' * * * since spent solvents reasonably are likely to contain other toxicants at levels of regulatory concern, and since we have not evaluated those wastes for these toxicants, we believe it inappropriate to remove these solvents from the hazardous waste list.'' In addition, the waste management association commenter argued that as part of the economic impact analysis associated with the 1999 HWIR proposal, there have been 51 different hazardous constituents associated with the F003 waste code. The commenter believed that if EPA lacked toxicological data on any of these constituents, then F003 could not be eligible for the exclusion once the ignitability characteristic was removed and the waste exhibited no other hazardous waste characteristics.

(2) Response to Comments on Eligibility of F003 Solvents for This Exclusion

EPA agrees with those comments that support F003 waste remaining eligible for this exclusion. Because F003 waste that contains 10% or more of the other F-listed solvents (F001, F002, F004, and F005) would also bear those waste codes, such wastes would not be eligible for the exclusion. The exclusions applies only to F003 wastes that do not contain 10% or more of these other solvents.

EPA is aware of the recent carcinogenicity study (referenced in the public comments) that was performed by the National Toxicology Program on ethylbenzene. Ethylbenzene is included in the Agency's on-going Integrated Risk Information System (IRIS) project (63 FR 68285, December 10, 1998). A focus of the IRIS project is to update selected chemical assessments by incorporating new scientific information and methods. The IRIS project consists of a process that determines the Agency's consensus position on the potential adverse health effects that may result from chronic or lifetime exposures to environmental contaminants. The carcinogenicity study on ethylbenzene, together with any other recent toxicological data, will be evaluated by the Agency as part of this process. Until that evaluation is completed, EPA does not believe it is appropriate to draw regulatory conclusions based on the referenced study.

With respect to the commenters' more generalized concerns about the possibility of toxic constituents in F003 waste, as explained above, EPA does not believe this possibility justifies the continued regulation of a waste that was listed for the sole reason that it is ignitable, where the waste is no longer ignitable and exhibits no other hazardous waste characteristic. F003 waste is unique among the listed solvents: the other listed solvents were listed on the basis of toxicity. F005 solvents were listed for both ignitability and toxicity. In fact, EPA decided to move two listed solvents (methanol and methyl isobutyl ketone) that were originally proposed to be regulated under the F005 listing to the F003 listing because EPA determined that they did not pose a significant toxicity risk, although they are highly flammable (45 FR 74884, November 12, 1980).

Since then, EPA has analyzed the toxicity risks that might be posed by F003 solvents when de-characterized. The Agency has researched the most recent data concerning the F003 solvents in the IRIS data base. None of the solvents in the listing are classified as carcinogens, but eight of the nine possess reference concentrations (RfC) and oral reference doses (RfD) for non-cancer risk. EPA used these RfCs and RfDs to calculate conservative screening-level health-based numbers (HBN) for those chemicals, and compared them to the relevant Universal Treatment Standards (UTS) these chemicals would need to meet under Land Disposal Restrictions. For seven of the eight chemicals (including ethylbenzene) the relevant UTS standards are much *lower* than the

conservative health-based numbers calculated for water and soil ingestion pathways. The health-based number for the remaining chemical, n-butyl alcohol, is only slightly lower than the UTS standard (3.3 mg/L water ingestion HBN vs 5.6 mg/L wastewater UTS).[15] Given the fact that the health-based numbers are conservative screening numbers, EPA does not believe this difference is of concern. Therefore EPA remains confident that excluding ignitable F003 solvents, when they have been decharacterized, is protective of human health and the environment.

Commenters also claimed that F003 solvents, because they are general use solvents, can carry with them various constituents other than the solvents themselves, and that this was a reason for listing the F003 solvents in the first place (see 50 FR 53317, December 31, 1985). EPA acknowledges that in the 1985 solvents final rule, we noted that additional toxic contaminants would likely be present in the spent solvent. We also stated, however, that we did not evaluate F003 wastes for other toxic constituents *that could be present* at levels of regulatory concern. Therefore, toxicity was a not a basis for listing F003 waste.

When the F003 listing was finalized in 1985, because it was listed solely for ignitability, mixtures of F003 waste and solid waste were eligible for the exemption for mixtures of waste listed for a characteristic that no longer exhibit any characteristic of hazardous waste. Expanding the exclusion to non-mixtures that similarly do not exhibit any characteristic would still be protective of human health and the environment. We do not think it makes sense to continue the anomaly of retaining regulation for non-mixtures of F003 wastes based on toxicity concerns when we have no record basis to support regulation for toxicity. Today's exclusion is also consistent with the approach taken in EPA's decision not to list 14 spent solvent wastes, in which EPA declined to focus on any toxic constituents other than those in the solvents themselves, despite the likelihood of other toxic constituents in the spent solvent waste. (63 FR 64372 (Nov. 19, 1998).[16]

[15] For the water ingestion pathway, EPA assumed a 71.8 kg adult with a 2.3 L/day intake (90th percentile), 350 days/yr frequency. For the soil ingestion pathway, EPA assumed a 16.6 kg child with 400 mg/day intake (upper percentile), 350 days/yr frequency. For more information, please see U.S. EPA *Analysis of Chemicals in Wastes Listed for Ignitability, Corrosivity, or Reactivity* memorandum to the docket from David Cozzie, Office of Solid Waste, November 22, 2000.

[16] EPA's determination was upheld at *EDF* v. *EPA,* 210 F.3d 396 (D.C. Cir. 2000).

D. Applicability of Land Disposal Restrictions (LDRs) to Excluded Wastes

(1) Comments on Applicability of Land Disposal Restrictions (LDRs) to Excluded Wastes

EPA received comments from 20 commenters in response to both the 1995 and the 1999 proposals concerning the applicability of LDRs to excluded wastes. Of those comments, eight were received from industries, four were from industry associations, two were from Federal Government Agencies, two were from State Agencies, one was from a consultant, one was from a waste management association, one was from a waste management company, and one was from an individual commenter. A summary of the specific issues raised by commenters is provided below.

Several commenters supported the EPA's proposed revision to the mixture and derived-from rules provided that the excluded waste meets land disposal restriction (LDR) requirements. One industry association noted that LDR standards assure that the waste is well treated. One State Agency believed that having similar wastestreams comply with the same requirements will achieve regulatory consistency as well as protection of human health and the environment.

Several commenters supported EPA's proposed revisions to the rules but did not support meeting LDR requirements. One industry commenter stated that applying LDRs to a waste which is excluded because it no longer meets the hazardous waste criteria is unnecessarily burdensome, costly and is a contradiction of the RCRA program requirements.

Two commenters said that the applicability of LDRs to both wastewater and nonwastewater forms of wastes should be both clear and identical. They felt that there is no justification for managing these wastes inconsistently.

Several of the comments dealt with whether excluded waste would need to be treated to meet LDR treatment standards for all underlying hazardous constituents (UHCs) under the existing rules. They felt that EPA should clarify that it did not intend to revise application of the current LDR rules without any discussion of why such a change would be necessary. One commenter emphasized that EPA has not provided a compelling case for requiring testing for UHCs or a clear methodology for implementing the requirements that are proposed. They stated that since these wastes are listed, generators have not been required to obtain information on underlying hazardous constituents. Obtaining this information would pose an undue burden for the generator, and they requested clarification on who would be responsible for verifying whether the waste in question meets the condition of the exclusion: the generator or the facility receiving the excluded waste.

Two industry association commenters referenced the Land Disposal Program Flexibility Act of 1996 (LDPFA) and its relationship to the proposed exclusion. Under LDPFA, solid wastes identified as hazardous based solely on a characteristic, are not prohibited wastes under the Land Disposal Restrictions program if they are managed in certain systems including a treatment system that subsequently discharges into waters of the United States pursuant to a CWA permit. The commenters further requested that EPA revise its proposed language modifying the mixture rule for wastes in proposed 40 CFR 261.3(a)(2)(ii) so that the land disposal restrictions program does not apply to wastes that are not prohibited. They argued that this revision is crucial to maintain the status quo for managing wastes listed solely for a characteristic in land-based units. Imposing the LDR program on such wastes would put many surface impoundments out of compliance because they are managing decharacterized listed wastes in land-based units that do not meet RCRA's minimum technology requirements.

(2) EPA Response to Comments on Applicability of Land Disposal Restrictions (LDRs) to Excluded Wastes

In proposing to expand the current exclusion for waste listed solely for a characteristic, EPA did not intend to change the way land disposal restrictions (LDRs) apply to the excluded waste. EPA agrees with those comments that support the continued application of LDR requirements to mixture and derived-from wastes listed solely for a characteristic of ignitability, corrosivity, or reactivity after they have become excluded. We are not imposing any new LDR requirements in this rule.

We agree that the treatment standards for UHC's do not apply in all cases, and have not changed the applicability of these requirements. In general, wastes that are both listed as hazardous waste and exhibit a characteristic only need to meet the treatment standard for the listed waste code. (40 CFR 268.9(b)). An exception occurs when the treatment standard for the listed waste code does not include a standard for the constituent that causes the waste to exhibit the characteristic. In this case, the waste must meet the treatment standards for all applicable listed and characteristic waste codes.

EPA disagrees with the comment that LDRs for wastewaters and nonwastewaters should be identical. We continue to support the existing different treatment standards for wastewaters and nonwastewaters. Such differences are based on waste treatability and differences in the Best Demonstrated Available Technology applicable to the waste.

Today's rule also does not broaden the applicability of LDRs. The revised language to 40 CFR 261.3 (g)(3) states, ''Wastes excluded under this section are still subject to part 268 of this chapter (as applicable), even if they no longer exhibit a characteristic at the point of land disposal.'' When the requirements of 40 CFR part 268 would not otherwise apply to a waste (for example, during treatment of certain characteristic wastes in a land-based unit), today's rule does not change that fact. In the case of wastes listed solely for ignitability, corrosivity, and reactivity that do not exhibit a characteristic at the point of generation, these wastes are considered to never have been hazardous and are not subject to 40 CFR part 268.

E. Applicability of Contained-In Policy to Excluded Wastes

1. Comment on Applicability of Contained-In Policy to Excluded Wastes

One commenter, the Department of Defense (DoD), requested that EPA clarify the interaction of the contained-in policy to the RCRA wastes that are listed solely for ignitability, corrosivity, and/or reactivity characteristics.

2. EPA Response to Comment on Applicability of Contained-In Policy to Excluded Wastes

The contained-in principle is the basis for EPA's longstanding interpretation regarding application of RCRA Subtitle C requirements to mixtures of contaminated media and hazardous wastes. Under the ''contained-in'' policy, EPA requires that soil (and other environmental media) be managed as hazardous wastes so long as they contain listed hazardous waste or exhibit a characteristic of hazardous waste. EPA's application of the ''contained-in'' policy to regulate media containing hazardous waste was upheld by the D.C. Circuit Court of Appeals in *Chemical Waste Management* v. *EPA,* 869 F2d 1526, 1539–40 (D.C. Cir. 1989). See the LDR Phase IV final rule 63 FR 28556, 28621 (May 26, 1998) for a detailed discussion of the contained-in policy and the Agency's reason, at the time, not to codify the contained-in policy for contaminated soil.

Today's final rule does not directly affect the implementation of the contained-in policy. However, wastes that are contained in contaminated media are eligible for the 40 CFR 261.3(g) exemption for wastes listed solely for a characteristic. Therefore, under today's final rule, contaminated media that contain a waste listed solely for a characteristic would no longer need to be managed as hazardous waste when it no longer exhibits a characteristic. However, consistent with the regulation of other decharacterized waste (and decharacterized contaminated media), it may remain subject to LDR requirements. (The final rule, by providing that wastes excluded under this section are subject to LDRs ''as applicable,'' applies the current rules regarding LDR applicability to soil containing hazardous waste. See, 40 CFR 268.49. For a detailed discussion of this subject, see 63 FR 28556, 28617 (May 26, 1998).)

IX. What Were the Major Comments on the Revision to 40 CFR 261.3 for Mixed Wastes, and How Has EPA Responded to Them?

A. 1999 Proposed Revision to 40 CFR 261.3 for Mixed Waste

In the 1999 proposal, EPA proposed a change to 40 CFR 261.3 that would exclude certain eligible mixed wastes (i.e., wastes that are both hazardous and radioactive) when they met the conditions outlined in the proposed 40 CFR part 266, Subpart N, which appeared in a separate Federal Register Notice. 64 FR 63464 (Nov. 19, 1999). EPA received comments from nine commenters in response to the 1999 HWIR proposal concerning the conditional exclusion from the mixture and derived-from rules for mixed waste. The commenters supported EPA's proposed conditional exemptions for low-level mixed waste (LLMW). Many of these commenters believed that such an exemption was implicit in the mixed waste proposal and necessary for the proposed mixed waste conditional exemptions to function effectively. Many of these commenters also noted that EPA's proposal would help eliminate much of the current regulatory overlap associated with LLMW. One commenter added that since the implementation of LLMW management under RCRA, it had been difficult to find treatment/disposal capacity for its limited quantities of mixed waste, and the proposal would improve safety, efficiency, cost and timeliness of LLMW management. Several commenters encouraged EPA to expedite its implementation.

However, two commenters (both Federal agencies) were concerned with the proposed regulatory language for implementing a conditional exemption from the mixture and derived-from rules for mixed waste. The commenters believed it would be more appropriate to pursue regulatory relief for low-level mixed waste (LLMW) via the standards proposed for 40 CFR part 266, Subpart N rather than within the definition of hazardous waste in 40 CFR 261.3. This proposed exemption within 40 CFR 261.3 would provide an inconsistency in the application of the MDF rules between wastes mixed with or derived-from the treatment of hazardous wastes and wastes mixed with or derived-from the treatment of LLMWs. The commenters noted that the proposed regulation for the transportation/disposal conditional exemption for mixed waste, section 266.305, exempts the waste from certain RCRA requirements (provided specified conditions are met), but does not exempt the waste from the definition of hazardous waste.

EPA appreciates the support expressed for the conditional exemption for mixed waste mixtures and derived-from wastes. In response to the apparent confusion about how the proposed regulatory language applies to these conditionally exempt mixed wastes, EPA has created a new section to 40 CFR 261.3, section (h), which more carefully explains how the definition of hazardous waste interacts with the mixed waste conditional exemption.

B. 1995 Comments on Conditional Exemptions for Mixed Waste

In EPA's 1995 HWIR proposal, we included a discussion of possible conditional exemptions for mixed wastes based on EPA's HWIR modeling, or on other conditions outlined in a proposal developed by the Department of Energy (DOE). EPA received comments from 45 commenters regarding this discussion, many of whom urged EPA to separate mixed waste from the HWIR rulemaking. DOE has since withdrawn its proposal, and EPA has developed a separate mixed waste exemption, which is published elsewhere in today's **Federal Register**. For a more detailed explanation of all the mixed waste comments submitted as part of the HWIR rulemakings, and EPA's response to those comments please see *Hazardous Waste Identification Rule: Revisions to the Mixture and Derived-From Rules Response to Comments Document.*

X. What Were the Major Comments on the Recommendations Submitted by the Chemical Manufacturers Association (CMA), and How Has EPA Responded to Them?

In August 1999, EPA received a paper from the Chemical Manufacturers Association (CMA) [17] describing five regulatory options for revising the mixture and derived-from rules. CMA forwarded these options seeking regulatory relief for some specific high-volume wastes that they believe are low-risk and feel that EPA could propose to exclude with very little delay. Although we did not have sufficient time to analyze these options in detail, we included a discussion of them in the 1999 HWIR notice to allow for public comment. Below is a short description of each option, a summary of the comments on the option, and EPA's response to the comments.

EPA is currently developing proposals related to two of the suggestions that we believe to be the most promising and straightforward to address: expanding the current headworks exclusion and excluding certain combustion residues. (see Sections X.A. and X.D. respectively). We are also considering additional proposals on the other suggestions, but we believe more analysis would first be necessary to decide how to address specific issues raised in the public comments. In addition, we will consider whether other opportunities exist for exempting low-risk waste from full Subtitle C regulation, including additional targeted exemptions and efforts to streamline the delisting program.

A. Expanding the Current Headworks Exclusion

One option involves an expansion of the current ''headworks'' exclusion in 40 CFR 261.3(a)(2)(iv)(A) and (B). The headworks exclusion excludes from the mixture rule wastewaters containing small quantities of particular F-listed solvents, based on the mass-balance flow of these solvents through the headworks of industrial wastewater treatment systems. CMA's options paper requests that this exclusion be amended in three ways.

First, CMA's suggested revision would allow direct monitoring of the actual concentration of spent solvents in untreated wastewater to demonstrate compliance. The current requirement is to perform a weekly mass balance of the solvents entering the system. Losses due to volatilization must be counted in the mass balance determination under the current system. We note that CMA's suggested wastewater monitoring would provide accurate data at the point the wastewater enters the treatment system, but the losses due to volatilization would not be counted in this approach.

Second, under CMA's suggested revisions, benzene, 2-ethoxyethanol, 2-nitropropane, and 1,1,2-trichloroethane would be incorporated into the list of chemicals for exclusion. These four chemicals were added to the 40 CFR 261.31 list of spent solvents in 1986 but the exclusion does not currently include these chemicals.

Third, under CMA's suggested revisions, multi-source leachate (F039) derived solely from the disposal of the spent solvents listed in 40 CFR 261.31 would be eligible for the exclusion.

(1) Summary of Comments on Expanding Headworks Exclusion

EPA received comments from 13 commenters in response to the discussion on expanding the headworks exclusion. Of those comments, two were received from industry, three were from industry associations, three were from utility companies or utility company associations, three were from State Agencies, one was from a Federal Government Agency, and one was from a waste management association. A summary of the specific issues raised by the commenters is provided below.

One state commenter noted that CMAS's suggested exclusion does not account for volatilization, an important factor considering the solvents involved, if the wastewater treatment system is not actually subject to Clean Air Act controls. In addition, they noted that CMA's suggested exclusion addresses whether and how RCRA should be modified in the wastewater treatment context, and they felt that this is a matter that could be addressed comprehensively following the completion of the surface impoundment study.[18] One waste management association commenter stated it was not clear what the potential environmental impact would be of expanding this exclusion to additional chemicals.

The rest of the commenters supported the CMA's recommendations for specific modifications to the mixture rule to expand the headworks exclusion in 40 CFR 261.3(a)(2)(iv)(A) and (B). Commenters noted that subsequent to the original headworks exclusion, additions were made to the F code solvent listings, but the corresponding changes were not made to the list of solvents in the headworks exclusion. For consistency, benezene, 2-ethoxyethanol, 2-nitropropane and 1,1,2-trichloroethane should be added to the list of solvents allowed under the headworks exclusion. One State added that the circumstances and reasoning that EPA used to support finalizing the original exclusion remain valid for these four solvents. Commenters also noted that they believed EPA would determine the appropriate headworks concentration (i.e., either 1 part per million or 25 parts per million). Also, it is appropriate, practical, and economical for a generator to manage small amounts of spent solvent wastes in a wastewater treatment system subject to regulation under sections 402 and 307 (b) of the Clean Water Act.

Nine of the commenters supported the use of direct monitoring of the actual concentration of spent solvents in untreated wastewater to demonstrate compliance with the headworks exclusion. Several commenters believed direct monitoring would facilitate documentation of compliance. A Federal commenter noted that the suggested changes would provide accurate data at the point the wastewater enters the treatment system, but still would allow generators who rarely discharge solvents into their wastewater systems to use the current method for verifying compliance. Several commenters believed that the mass-balance approach gives rise to a number of problems due to the varying degrees of precision in the underlying measurements and, therefore, deters use of this exclusion. Instead, direct sampling and analysis methods are much more straightforward to implement and would provide more accurate information about what actually is being discharged to treatment systems. A State commented that direct monitoring provides the most definitive information on the concentration levels of hazardous constituents in a waste. Direct monitoring would allow generators to apply the exclusion to its full intended regulatory limit. An industry commenter recommended that compliance with the regulatory levels be measured on a rolling average basis since flows may be variable. Several commenters noted that they do not believe that direct monitoring would encourage volatilization. They noted that EPA did not state directly that the current measurement scheme needed to account for volatilization when the headworks exclusion was finalized and it is not part of the current regulatory

[17] CMA has since changed the name of the organization to the American Chemistry Council (ACC).

[18] Note: EPA's surface impoundment study was completed March 2001. See U.S. Environmental Protection Agency. *Industrial Surface Impoundments in the United States.* EPA530–R–01–005. Washington, D.C. March 2001.

language. However, these comments recognized that over the years, EPA has explained in preamble language and interpretive letters that it considered accounting for volatilization losses to be necessary to prevent facilities from volatilizing solvents in order to be eligible for the exclusion. In the years subsequent to the statement, EPA has issued a number of regulations addressing air emissions of organics, including the listed solvents. Because EPA has addressed these potential air emissions by regulations which focus specifically on these emissions, the commenters felt that there is no need for the headworks exclusion to have to account for them as well.

One State commenter did not support the inclusion of multi-source leachate (F039) in the headworks exclusion, even though the leachate might be derived from the disposal of solvent wastes. The commenter noted that leachate might contain any variety of hazardous constituents, due to the presence of characteristic wastes or non-hazardous wastes. The commenter further noted that it would be difficult to determine whether the headworks exclusion, if modified in this manner, would protect human health and the environment sufficiently. The commenter did state that if the discharge is regulated under the Clean Water Act (CWA), this may provide a reasonable amount of assurance with respect to exposure paths, relating to the wastewater discharge.

Six of the commenters supported extending the exclusion to multi-source leachate (F039) derived solely from the disposal of the spent solvents in 40 CFR 261.31. A Federal commenter noted that in many cases, leachate is contaminated with barely detectable concentrations of F-listed solvents, yet the leachate still is classified as hazardous waste. By allowing the wastewater to be discharged for treatment to a wastewater treatment or pre-treatment system regulated under the CWA, EPA would encourage remediation by lowering treatment costs. The commenter also stated that EPA must believe that the 1 ppm/25 ppm concentration limits established under the existing rules are protective of human health and the environment, so extending those limits to wastes derived from the land disposal of certain listed solvents should be adequately protective.

Several commenters noted that the advent of the multi-source leachate waste code simplified some hazardous waste management by applying the single listing code to hazardous waste leachate. However, this streamlining did create some unintended consequences. Leachate generated solely from F001–F005 solvents no longer qualified for the headworks exclusion, even though the composition of the leachate was virtually identical to dilute non-leachate F001–F005 streams. Therefore, even though F039 leachate derived solely from F001–F005 wastes are exactly the same in chemical composition as the wastes from which they are derived, they cannot be treated in the same treatment train. They must be segregated and handled in separate tank-based systems or shipped off site for treatment and disposal causing additional cost but providing no additional environmental protection. One industry commenter recommended that EPA issue a technical correction or clarification notice with or before promulgating the final HWIR rule to address this problem. Under CMA's recommendation, the headworks exclusion rationale for the solvent wastes from ongoing production processes would be applied equally to solvent wastes leaching from a landfill. Both are treated equally well in the wastewater treatment plant at these low concentrations, so there is no justification for regulating them differently.

(2) EPA Response to Comments on Expanding the Headworks Exclusion

EPA agrees that there is merit in proposing to expand the current exclusions in 40 CFR 261.3(a)(2)(iv)(A) and (B) (the ''headworks'' exclusion) to include the four solvents listed in 1986: benzene, 2-nitropropane, 2-ethoxyethanol, and 1,1,2-trichloroethane, and we are currently developing a proposal on such an expansion. In the proposal, EPA will take into account the issues raised by the commenters, including environmental impacts of the expanded exclusion, and the use of any available surface impoundment study data. In the meantime, we welcome any data or additional feedback from the public on this topic.

We will also evaluate in this proposal the issue of measurement versus mass balance calculation as a part of the implementation of the headworks rule. EPA agrees that in the past 20 years, significant new Clean Air Act regulations have come into effect that may address some of the concerns about deliberate volatilization. In developing a proposed revision to the monitoring requirements for the headworks rule, we would take into account the issue raised by the commenters, including the issues concerning volatilization. We welcome any additional data the public has to support such a change.

EPA is also interested in possible applications in which solvent-only landfill leachate may be sent to a wastewater treatment facility. We are concerned, however, about possible difficulties in determining whether a landfill has received only solvent wastes. As part of the investigation, EPA would need more information characterizing possible ''solvent waste only'' landfills. We welcome any additional data the public has on these landfills.

B. Excluding Hazardous Waste Leachate

Another of the suggested regulatory options involves leachate derived from the land disposal of listed hazardous waste which is subsequently managed in a system regulated under the Clean Water Act. CMA argues that the leachate is both physically and chemically dissimilar from the wastes that were originally listed. Under the option presented, leachate would not be hazardous, even when generated from the treatment, storage or disposal of hazardous waste, unless it exhibited one or more of the hazardous waste characteristics of 40 CFR Part 261, Subpart C.

(1) Comments on Excluding Hazardous Waste Leachate

EPA received comments from eight commenters in response to excluding leachate. Of those comments, three were received from industries, one was from an industry association, three were from State Agencies, and one was from a waste management association. A summary of the specific issues raised by commenters is provided below.

The waste management association did not support the exclusion, noting that treatment tanks that are part of a Clean Water Act (CWA) system already are conditionally exempt. Thus, it was not clear to the commenter why a more expansive exclusion was advisable, particularly because leachate from hazardous wastes ''may often contain toxic constituents that are not subject to NPDES discharge limits or water quality standards.'' Also, one State did not support the exclusion noting that many organics of concern are not covered by the toxicity characteristic. Furthermore, the State commenter believed that it would be inappropriate to exclude these wastestreams without examining the results of the surface impoundment study, particularly without any supporting data on the physical/chemical properties of the leachate and its associated risks. Finally, these State comments claimed that there is no generic way to tell if these leachates will pose a problem. They could be very

different from unit to unit depending upon what type of waste has been placed in the unit. The commenter also felt that there could be an air emission problem or the leachate could cause the sludge to become hazardous. Instead, the State commenter thought industries should go through a case specific delisting for these wastes.

One State commenter did not understand CMA's proposal to exclude leachate from the derived-from rule. Currently, F039 leachate waste is subject to Part 268 land disposal restriction requirements and could be treated onsite in a tank or container within 90 days of generation without a permit. If this treated waste was an industrial wastewater discharge that was a point source discharge subject to regulation under section 402 of the Clean Water Act, it would be eligible for the 261.4(a)(2) exclusion. In that case the wastewater would not be a solid waste. The State wondered if CMA was proposing that F039 be exempt from LDR requirements. If that was the case, the State did not support such a recommendation.

One State commenter stated that there may be merit in excluding leachate resulting from the land disposal of a listed hazardous waste when the leachate is subsequently managed in a wastewater treatment system regulated under the CWA. However, to make a definitive decision, the State expressed a need to evaluate constituent concentration data, current management practices, environmental injury cases caused by the residues, and whether the residues commonly exhibit a hazardous waste characteristic. Since (1) the leachate is generated from landfills where only treated hazardous wastes are disposed, and (2) bonafide treatment has occurred and the residues are physically and/or chemically different from the hazardous wastes they were generated from, the State believed it was appropriate to view the residues as newly generated wastes and impose RCRA regulation only if the waste exhibited a hazardous waste characteristic.

The rest of the commenters believed that EPA should consider leachate from hazardous waste landfills to be a newly generated waste rather than derived-from waste. As a newly generated waste, it would be subject to regulation if it failed one or more hazardous waste characteristics, but would no longer be subject to hazardous waste regulation solely because the landfill accepted listed hazardous wastes. Several commenters noted that most POTWs would not accept direct discharges of listed hazardous waste, even if the leachate met all applicable effluent guidelines and other standards. As a result, several commenters noted that they must use costly and unnecessary incineration or other treatment at off-site facilities. In addition, the transportation and management from sending the wastes off-site actually may increase environmental risks and energy usage relative to the protective and cost-effective management in industrial wastewater systems. Several commenters noted that both landfills and land treatment units, as defined by RCRA, generate a leachate when constructed with a bottom liner. Leachate from either type of unit should qualify for the exclusion so long as it did not fail for a hazardous characteristic and the wastewater treatment system receiving the leachate was subject to regulation under the CWA. Two commenters also recommended as an alternative to considering leachate from hazardous waste landfills to be a newly generated waste, that EPA make it eligible for the headworks exclusion.

(2) EPA Response to Comments on Excluding Hazardous Waste Leachate

At this time, EPA is still considering the suggested regulatory exclusion for leachate derived-from landfilled hazardous waste as well as other specific exemption options, but we first need to evaluate several important issues. As noted in the comments, most hazardous waste leachate is regulated under a separate waste code, F039. To date, we have received no information that would cause us to reconsider that listing, although we would welcome any data that might be helpful in such a re-evaluation. However, in the most recent EPA study of landfill leachate characteristics (65 FR 3007, January 19, 2000), we found considerable differences between the leachate samples from hazardous and those from non-hazardous landfills in both numbers of constituents of concern and their concentrations. Hazardous waste landfill leachate contained a greater number of constituents than non-hazardous waste landfill leachate, and constituents found in both hazardous and non-hazardous waste landfill leachate were generally present in hazardous waste landfill leachate at concentrations an order of magnitude higher than those found in non-hazardous waste landfill leachate.[19] As noted in the comments, these pollutants can include many organic hazardous constituents not covered by the Toxicity Characteristic. Absent a risk assessment, it is not possible to determine whether the levels of these constituents pose unacceptable risk. However, the presence of these constituents is a strong indication that more study would be needed before developing an exemption for hazardous waste leachate.

C. Excluding Hazardous Waste Aggressive Biological Treatment Residues

Another suggested regulatory option involves excluding residues from the biological treatment of listed hazardous wastewaters. CMA argues that theses wastes are both physically and chemically dissimilar from the wastes that were originally listed. In addition, CMA notes that biological treatment can greatly reduce or eliminate organic chemicals. Under the options presented in CMA's discussion papers, these wastes would not be hazardous, even though they are generated from the treatment, storage or disposal of hazardous waste, unless they exhibit one or more of the hazardous waste characteristics of Subpart C of 40 CFR part 261.

(1) Comments on Excluding Residues From Aggressive Biological Treatment of Hazardous Waste

EPA received comments from 10 commenters in response to the CMA recommendation to exclude aggressive biological treatment residues from the derived-from rule. Of those comments, four were received from industries, two were from industry associations, three were from State Agencies, and one was from a waste management association. A summary of the specific issues raised by commenters is provided below.

The waste management association did not support excluding sludges derived from the biological treatment of listed hazardous wastes. The commenter noted that the sludges typically contain concentrations of heavy metals that warrant further treatment and Subtitle C disposal. EPA's listing background document for F006 electroplating sludges, for example, provides data on the presence of lead, cadmium, chromium and other toxic metals in such wastewater treatment sludges.

Two States did not support the exclusion, noting that these sludges can continue to pose a threat to human health and the environment and should continue to be subject to the derived-from rule. The States also believed that these wastes should meet land disposal restriction (LDR) treatment standards, just as any other listed hazardous waste

[19] Development Document for Final Effluent Limitations Guidelines and Standards for the Landfills Point Source Category, EPA–821–R–99–019, U.S. EPA, January 2000.

is required to meet a treatment standard before being disposed in a permitted Subtitle C facility. One State noted that EPA proposed the retention of the mixture and derived-from rules in part because of the potential toxicity of wastewater treatment sludges. (See 64 FR 63389, November 19, 1999).

One State commenter noted that there may be merit in excluding aggressive biological treatment residues. However, to make a definitive decision, the State would need to evaluate constituent concentration data, current management practices, environmental injury cases caused by the residues, and whether the residues commonly exhibit a hazardous waste characteristic. Since wastewater treatment is a bonafide treatment method proven to detoxify or otherwise treat hazardous waste and the residues are physically and/or chemically different from the hazardous wastes they were generated from, the State believed it was appropriate to view the residues as newly generated wastes and impose RCRA regulation only if the waste exhibited a hazardous waste characteristic.

The rest of the commenters supported excluding sludges derived from the biological treatment of listed hazardous wastes. Many commenters noted that industrial biosludges currently are overmanaged as hazardous wastes at a high cost to industry. Several commenters added that residues from biological treatment processes have reduced organic constituent concentrations significantly relative to the original waste. Commenters noted that most listed wastewaters are 99% water and are therefore substantially different in terms of potential for environmental harm than a non-wastewater form of the same waste. Also, residues derived from aggressive biological treatment are fundamentally different (both chemically and physically) from the originally listed wastes and these residues should be considered a new point of generation. One commenter submitted data on the concentration of chemicals in a combined treatment sludge.

Additionally, commenters claimed that in recent hazardous waste listings, EPA has recognized that treatment sludges do not necessarily present any significant environmental hazard even when there is sufficient hazard in the waste as generated to warrant listing by EPA (e.g., wastewater treatment sludges from carbamates, anthraquinone, and chlorinated aliphatics). Commenters also noted that public reporting of these very large volumes of derived-from waste misleads the public over the amount of actual hazardous waste in their communities.

Several commenters believed that there should not be a specific contingent management requirement associated with the excluded biosludge. Rather, the sludge would be subject to state industrial non-hazardous waste RCRA (Subtitle D) programs, including restrictions on industrial non-hazardous waste landfilling, combustion and other management options. Since industrial biosludge resulting from an aggressive biological treatment system is not significantly different from sewage sludge, the commenters expected that any restrictions placed on the use of sewage sludge would likewise apply to excluded sludge.

A few commenters pointed out that the LDR program for characteristic wastes has over the years established new points of generation. The commenters noted that in the LDR program, EPA recognized that various treatment residuals differ from the wastes from which they are derived and should not continue to be regulated as the same wastes. In at least three other situations, EPA has made a specific determination that the generation of wastewater treatment biosludge constitutes a new point of generation, generally on the basis that the wastewater being treated falls into one treatability group and the resultant sludge into another. They are: (1) Sludge from the treatment of U154 contaminated groundwater—The sludge is considered newly generated waste because it is a different treatability group than the wastewater being treated—sludge generated from treating non-ignitable wastewaters not derived from hazardous waste (03/21/96 Berlow, EPA to Day, Bryan Cave, LLP); (2) LDR notification requirements for wastewaters and sludges—LDR requirements apply only to wastes that are hazardous at the point of generation. Non-hazardous sludges removed from a wastewater treatment unit require no LDR notification. The requirement to identify and treat for underlying hazardous constituents (UHCs) is not applicable to wastewaters managed in centralized wastewater treatment systems subject to the CWA or to sludges that are not hazardous at the point of generation (05/01/97 Cotsworth, EPA to Dolce, Award Environmental Inc.); and (3) applicability of land disposal restrictions to tank-based wastewater treatment systems—LDRs do not apply to waste managed in systems that are entirely tank-based; sludge generated from wastewater treatment belongs to a different treatability group, and is therefore a newly generated waste that should be evaluated at the point of generation (03/29/97 Berlow, EPA to Day, Bryan Cave, LLP).

(2) EPA Response to Comments on Excluding Residues From Aggressive Biological Treatment of Hazardous Waste

EPA is considering a tailored exclusion for biological treatment residues, but does not believe that a blanket exclusion from the mixture and derived-from rules is appropriate for such wastes. Not all wastestreams are amenable to biological treatment, and the composition of the residuals generated from biological treatment would vary greatly depending on the influent and on the efficacy of the treatment system.

We have, in the past, determined that biological treatment systems are inappropriate for metals and could result in impermissible dilution under the LDR program.[20] We have also denied a delisting petition for K035 sludges resulting from aerated biological treatment of creosote in a surface impoundment in part because of downgradient groundwater contamination.[21] In addition, we have information that facilities have attempted to avoid generating F037 and F038 wastes by adding minimal aeration to primary treatment units and claiming the sludges from these units as excluded.[22]

However, EPA believes there may be merit to the idea of regulating certain types of biological treatment residues differently. As noted in the comments, we have in the past excluded certain types of biological treatment wastes from regulation (see, for example, 40 CFR 261.3(c)(2)(ii)(D)). There may be other types of waste similarly amenable to biological treatment. Before developing such a regulatory proposal, EPA would first gather and analyze data on biological treatment waste. Therefore, any such data would be welcomed by the Agency.

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[20] EPA 1990. *LDR Determination of Waste Stream Dilution,* Letter from Jeffery Denit, Deputy Director, Office of Solid Waste to Bruce Smith, Director, Office of Hazardous Waste Programs, EPA Region III, October 14, 1990. [FAXBACK 13414, PPC 9551.1990(06)]

[21] EPA 1987. *K035 Listing and Inclusion of Sludges from Biological Treatment of Creosote Production Wastes,* Letter from Bruce R. Weddle, U.S. EPA, to Jordan Dern, Koppers Company, Inc., December 11, 1987. [FAXBACK 13105, PPC 9444.1987(52)].

[22] U.S. EPA 1991. *Draft Region VIII Policy on ''Aggressive Biological Treatment'',* Letter from Robert L. Duprey, Director, Hazardous Waste Management Division (EPA Region VIII) to Sylvia K. Lowrance, Director, Office of Solid Waste, April 19, 1991 (Ref: 8HWM–RI)

D. Excluding Hazardous Waste Combustion Residues

Another of CMA's suggested options involves excluding residues from the combustion of listed hazardous waste. CMA argues that these wastes are both physically and chemically dissimilar from the wastes that were originally listed. In addition, CMA notes that combustion can virtually eliminate organic chemicals. Under the options presented in CMA's discussion papers, these wastes, which would include combustion ash, slag, air pollution control residue and scrubber water, would not be hazardous, even though they are generated from the treatment, storage or disposal of hazardous waste, unless they exhibit one or more of the hazardous waste characteristics of 40 CFR part 261, Subpart C.

(1) Comments on Excluding Hazardous Waste Combustion Residues

EPA received comments from 15 commenters in response to the CMA recommendation to exclude hazardous waste combustion residues. Of those comments, seven were received from industries, two were from industry associations, four were from State Agencies, one was from a waste management company, and one was from a waste management association. A summary of the specific issues raised by commenters is provided below.

One waste management association and two State commenters did not support excluding combustion residues, noting that there is a great deal of variability in combustion residues. While some organic compounds are destroyed effectively by the combustion process, the residue may contain persistent constituents (e.g., dioxins and metals) that are toxic. Accordingly, while the combustion byproducts may be physically and chemically dissimilar from the listed waste it is derived from, the byproducts have toxic properties that could cause environmental degradation. The commenters believed that relying on the TC by itself fails to provide adequate protection of human health and the environment. The commenters mentioned that not all metals of concern are covered by the TC. They also noted that the TC only measures potential risks via the groundwater pathway, and it is not definitive that groundwater is the driving risk pathway for these wastes. Because the TC approach does not comprehensively evaluate potential risks, wastes that do not exhibit hazardous waste characteristics are not necessarily non-hazardous. In addition, one State commenter believed it was prudent to wait for EPA's anticipated action on proposed combustion residues to address the physical and chemical properties of these wastes before any action is taken on CMA's proposal.

Two State commenters stated that there may be merit in excluding residues from the combustion of listed hazardous wastes. However, to make a definitive decision, one State would need to evaluate constituent concentration data, current management practices, environmental injury cases caused by the residues, and whether the residues commonly exhibit a hazardous waste characteristic. Since bonafide treatment has occurred and the residues are physically and/or chemically different from the hazardous wastes they were generated from, the State believed it was appropriate to view the residues as newly generated wastes and impose RCRA regulation if the waste exhibited a hazardous waste characteristic. Another State commenter believed an exclusion for combustion residues could be appropriate if the combustion takes place in a permitted (not interim status) hazardous waste combustion device; any listed wastes are listed for organic hazardous constituents only; the residual must not exhibit any characteristics; and the residues meet LDRs, including standards for underlying constituents. This approach would protect human health and the environment fully and would allow many combustion residues to exit Subtitle C regulation once LDRs are met.

The rest of the commenters believed that EPA should consider residues from hazardous waste combustion to be a new point of generation. These combustion residuals substantially differ in their physical and chemical makeup from the original listed hazardous wastes from which they are derived. Subtitle C regulation is not needed for such combustion residuals, especially if the residues do not exhibit hazardous characteristics. Instead, the residues can be managed adequately and protectively as industrial non-hazardous waste or discharged under the Clean Water Act. The commenters believed that the high cost of regulating these materials as hazardous waste purchases little or no increased protection of human health and the environment. The hazardous waste combustion process destroys virtually all of the organics in the listed wastes from which these residuals are derived, and the Toxicity Characteristic limits for metals are virtually the same as the health-based limits EPA-established for excluding Bevill wastes from Subtitle C regulation. One commenter submitted information on the operating parameters and limits for their combustion unit and the concentrations of the sludge from incinerator scrubber water generated.

One industry commenter noted that in combustion-related rulemakings, EPA consistently has maintained that well-operated and maintained combustion units can achieve high combustion efficiencies and can be operated in a manner that is protective of human health and the environment. Therefore, the commenter recommended the exclusion be limited to residues from units that continuously monitor stack emissions of CO, and do not exceed a CO level of 100 ppmv measured as an hourly rolling average.

While agreeing with CMA's proposal, one association commenter believed it should be extended to combustion residues from facilities operating pursuant to 40 CFR part 266, subpart F, specifically residues from precious metal reclamation operations. The commenter noted that the recovery of precious metals from hazardous waste is not a TSDF operation, and the units are not permitted under the same CFR sections. The commenter added that precious metal-bearing residues also are environmentally safe for two additional reasons: (1) Precious metal-bearing residues must not exhibit one or more of the characteristics of hazardous waste and (2) the residues must contain economically significant amounts of precious metals (to partake of the authority of 40 CFR 266.100(f)), and thus such wastes will be further reclaimed rather than disposed, ensuring environmentally protective management.

One commenter supported the use of the TCLP extract concentration limits in Appendix VII to 40 CFR part 266 as the criteria for excluding combustion residues. Several commenters also believed that solid residues from hazardous waste combustion units that do not exhibit any toxicity characteristic should be considered industrial non-hazardous waste. As such, the materials would be subject to state industrial non-hazardous waste programs.

(2) EPA Response to Comments on Excluding Hazardous Waste Combustion Residues

EPA is considering a possible exclusion for certain combustion residues, but does not believe that a blanket exclusion from the mixture and derived-from rules is appropriate for such wastes. Although hazardous waste combustors must meet at least 99.99% DRE (destruction and removal efficiency), metals and certain organics may only be transferred to a residue.

The constituents can become significantly concentrated in the residue. EPA does not believe that stack emissions are a reliable measure of the risk posed by the combustion residue; in fact, as technology improves the removal capability of air pollution control devices, the resulting residue will likely have greater concentrations of hazardous constituents and may pose unacceptable risks if mismanaged. In addition, several of the mixture and derived-from waste damage cases that EPA has identified are a result of improper disposal of combustion residues.[23]

In addition, EPA is particularly concerned about the possible formation of dioxins and furans during hazardous waste combustion. In the September 1999 combustion rule, we noted that there is ''a considerable body of evidence'' to show that dioxin and furan compounds can be formed in the post-combustion regions of hazardous waste combustors (see 64 FR 52994). Because of this concern, we have added these dioxin and furan compounds to Appendix VIII of 40 CFR part 266, which lists products of incomplete combustion (PICs) likely to be found in stack effluents.

However, EPA is considering a proposed tailored exclusion for certain combustion residues. For example, EPA is currently developing for public comment a proposed exclusion that focuses on wastes that have been slagged to liquefaction. These slagged wastes are unique because the high temperatures associated with liquefaction (2100°F, typically) appear to eliminate organic chemicals, including PICs, and generate a slagged residue which is a glassy, liquid, molten material that, when cooled, forms a potentially durable, homogeneous, solid mass. This combination of elimination of organic chemicals and change in physical form (which can reduce risk from non-groundwater pathways) make these slagged residues potential candidates for de-regulation. However, the liquefaction process does not reduce the concentration of toxic metals in the waste, which we would need to evaluate for potential risks to human health and the environment. EPA is planning to address this issue, as well as other possible tailored exclusions for combustion residues, in the upcoming proposal.

[23] *See* table 1, EPA 2000. *Releases of Hazardous Constituents Associated with Mixture and Derived-from Wastes (An Update)* U.S. EPA, April 2000.

E. Expanding the Current De Minimis Exclusion

A final regulatory option to revise the mixture and derived-from rules would expand a current exclusion for ''*de minimis*'' losses that result from the manufacture of commercial chemical products. The current exclusion, found in 40 CFR 261.3(a)(2)(iv)(D), excludes small losses of a commercial chemical product that can result from normal handling of the chemicals during the manufacturing process. The existing exclusion applies to commercial chemical products or intermediates, when they are lost during the manufacturing operation and are subsequently managed as a wastewater subject to regulation under the Clean Water Act (CWA) (see 46 FR 56586). The suggested expansion of this option would also exclude small losses from the normal handling of all listed hazardous wastes (instead of just commercial chemical products) when managed as a wastewater under the CWA. One rationale for the current ''de minimis'' exclusion is that a facility has little economic incentive to allow spills, leaks or other losses of commercial products. With respect to wastes, CMA believes that tank, container and air emission management standards of 40 CFR parts 264 and 265, subparts I, J, BB, and CC serve to encourage safe management of these wastes.

(1) Summary of Comments on Expanding the Current De Minimis Exclusion

EPA received comments from 15 commenters in response to the suggested expansion of the de minimis exclusion. Of those comments, six were received from industries, four were from industry associations, three were from State Agencies, one was from a Federal Government Agency, and one was from a waste management association. A summary of the specific issues raised by commenters is provided below.

Three commenters did not support the exclusion, believing that the exclusion might serve as an incentive for generators to spill or leak listed wastes into non-hazardous wastewater systems if those wastes were eligible for an exclusion. The current exclusion exists for commercial chemical products and companies typically ensure that raw materials/products are handled in a manner which would minimize losses, as these materials/products are valuable. The commenters did not believe that companies necessarily would take the same amount of care to prevent losses of listed wastes, if those wastes were excluded from Subtitle C.

One State commenter supported the exclusion. However, the State believes that rinsate from large hazardous waste containers that are rendered empty should be outside the definition of a de minimis loss. Large containers such as tanker trucks could contain substantial quantities (possibly hundreds of gallons) of hazardous waste. Such a volume of hazardous waste is outside the scope of losses that should be defined as de minimis and should not be defined as such.

One industry commenter stated that it was not clear from the preamble discussion what was meant by ''rinsate from empty containers or from containers that are rendered empty by that rinsing.'' The commenter noted that rinsate from containers that held hazardous waste ''generally contains concentrations of hazardous constituents which are at least as high as the original waste'' and may contain significant quantities of solids. The quantities used to rinse containers of this type also may be significant depending upon the level of contamination in the container. In some cases it is not possible to clean a container to the point of being empty under the RCRA regulations and the container has to be disposed of as hazardous waste. The commenter believed that this issue must be clarified further before any exclusion could be considered. An industry association commenter also noted that the CMA proposal did not identify adequately the wastes for which the exclusion would operate. Since RCRA-empty container rinsate is already excluded, the commenter believed it should be specified that any exclusion need only address acute hazardous waste rinsate.

The rest of the commenters supported expanding the de minimis exclusion to all listed wastes. Several commenters believed that the exclusion could be extended beneficially to cover the very small losses from the normal handling of all listed wastes. The stringent regulation of hazardous waste handling at the site of generation means that few losses of this type would be expected to occur. The ability to manage de minimis losses of listed wastes as non-hazardous would ease RCRA compliance significantly without compromising the integrity of the NPDES wastewater treatment system or protection of human health and the environment.

The commenters noted that there was no reason to assume that a non-hazardous industrial wastewater treatment facility was any less capable of providing adequate treatment of the hazardous constituents found in listed wastes. EPA's stringent container and

tank management standards in 40 CFR parts 264 and 265 subparts I and J, and air emission standards in subpart CC, serve as powerful incentives to properly manage these wastes to minimize the occurrence of ''de minimis'' losses. The Federal commenter supported the expansion, noting that it would provide to military installations the same level of regulation as is currently applicable to manufacturing industries. One industry commenter recommended that facilities wishing to take advantage of this exclusion be required to develop and implement written Best Management Practices (BMP) for all loading, unloading and transfer operations which are designed to minimize spills and prevent abuse of the exclusion.

One commenter questioned why EPA never has set out a scientific rationale by which it reserves the discriminatory use of the de minimis rule to those engaged in the manufacturing process and denies it to all others, including stand-alone bulk liquid commercial chemical storage terminals. The commenter also suggested that de minimis losses include those from normal material handling operations (e.g., spills from the unloading or transfer of materials from bins or other containers, leaks from pipes, valves or other devices used to transfer materials); minor leaks of process equipment, storage tanks or containers, leaks from well-maintained pump packings and seals; sample purgings; relief device discharges; discharges from safety showers and rinsing and cleaning of personal safety equipment; and rinsate from empty containers or from containers that are rendered empty by that rinsing.

Another commenter believed that there would be significant benefits from allowing de minimis losses of commercial chemical products from laboratories to be covered by the current regulatory exclusion. The types of commercial chemical products being used and tested in the laboratory also could be expected to be amenable to effective treatment in an on-site wastewater treatment system. The commenter noted that significant time, effort and cost is involved in segregating and capturing these types of de minimis losses from on-site laboratories.

(2) EPA's Response to Comments on Expanding the Current De Minimis Exclusion

EPA is considering the possibility of expanding the current de minimis exclusion for wastes managed in a wastewater treatment system subject to the Clean Water Act. However, EPA is concerned about the possible negative incentives that might result from extending the de minimis exclusion to wastes listed in 40 CFR 261.31 and 261.32 (F and K wastes, respectively). As noted in the comments, there is a direct economic incentive to ensuring that raw materials/products are handled in a manner which would minimize losses, as these materials/products are valuable. This incentive does not exist for hazardous waste. The concept of ''de minimis'' is also variable, depending on the quantities of material handled and the relationship of those quantities with the flowrate of the facility's wastewater treatment plant. However, EPA realizes that separation of small leaks of certain hazardous wastes can sometimes be impractical.

One possible approach would be to base the concept of ''de minimis'' on some fixed quantity of the waste, such as a Reportable Quantity (RQ) in Superfund regulations (see 40 CFR 302.4 and Table 302.4). By statute, all hazardous wastes must be given an RQ. EPA may pursue the concept of de minimis related to RQs (or some fraction or multiple thereof) as we consider this issue further. In pursuing such a change, EPA would do so through a proposed rulemaking.

In conclusion, EPA is currently developing proposals related to two of the suggestions that we believe to be the most straightforward to address: expanding the current headworks exclusion and excluding certain combustion residues (see Sections X.A. and X.D. respectively). We will also consider developing additional proposals on the other suggestions as well as other targeted exemptions, but we believe more analysis would first be necessary to decide how to address specific issues raised in the public. EPA welcomes any information or data that would help us in developing these analyses.

State Authorization

XI. How Will Today's Regulatory Changes Be Administered and Enforced in the States?

Under section 3006 of RCRA, EPA may authorize qualified States to carry out the RCRA hazardous waste program within the State. Following authorization, we maintain independent enforcement authority under sections 3007, 3008, 3013, and 7003 of RCRA, although authorized States have enforcement responsibility. An authorized State could become authorized for today's regulatory changes by following the approval process described under 40 CFR 271.21. See 40 CFR part 271 for the overall standards and requirements for authorization.

We are finalizing the retention of the mixture and derived-from rules. Most states have already received authorization for the mixture and derived-from rules as they currently stand. The rules are already in effect in those authorized States. Those states that are already authorized for the mixture and derived-from rules do not need to obtain authorization for those rules again. We are also revising those rules under the authority of sections 3001(a), 3002(a), and 3004(a) of RCRA. These revisions will not go into effect in authorized States until they adopt the revisions and receive authorization from us for the revision to their regulations.

None of today's revisions are more stringent or broaden the scope of the existing Federal requirements. Authorized States are not required to modify their programs when we promulgate changes to Federal requirements that are less stringent than, or that narrow the scope of, existing Federal requirements. This flexibility stems from RCRA section 3009, which allows the States to impose (or retain) standards that are more stringent than those in the Federal program. (See also 40 CFR 271.1(i)). Therefore, States are not required to adopt the revisions to the mixture and derived-from rules in today's rule, although EPA will strongly encourage their adoption.

Administrative Requirements

XII. How Has EPA Fulfilled the Administrative Requirements for This Rulemaking?

Several statutes and executive orders apply to rulemaking. Below is an explanation of how we address the requirements in those provisions:

A. Executive Order 12866: Determination of Significance

Under Executive Order 12866 (58 FR 51,735 (Oct. 4, 1993)), EPA must determine whether a regulatory action is ''significant'' and, therefore, subject to OMB review and the other provisions of the Executive Order. The Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or rights and obligations or recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Pursuant to the fourth term of Executive Order 12866, we have determined that this rule is a ''significant regulatory action'' because there are novel policy issues arising out of legal mandates. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the docket to today's rule.

Although today's final rule is not ''economically significant,'' the Agency prepared an economics background document in support of today's rule, titled *Economic Assessment of the U.S. EPA's 2001 Final Rule Revising the Mixture and Derived-From Rules.*

There are currently 29 hazardous waste codes within the RCRA program listed solely for ignitability (I), corrosivity (C), and/or reactivity (R) characteristics. Today's rule excludes these wastes from RCRA Subtitle C regulation, if such wastes are de-characterized and meet the associated LDR treatment standards.To estimate the potential economic impact of excluding these 29 characteristically-listed RCRA waste codes, we analyzed the type and quantity of industrial hazardous wastes contained in the two databases: the 1986 ''Generator Survey'', and the 1996 ''National Hazardous Waste Constituent Survey.'' These two databases are described in the Economic Assessment background document.

This exclusion is expected to benefit the relevant segment of the RCRA regulated community by reducing the cost of shipping and disposing these de-characterized wastes. This potential cost savings is modeled in this study as consisting of two components:

(1) The difference between the cost for disposal of treatment residuals from these 29 waste codes in hazardous landfills (i.e., current or ''baseline'' practice), compared to the cost for disposal in nonhazardous landfills under this exclusion.

(2) The reduction in burden hours and associated burden cost for no longer requiring preparation, transmitting and filing of truck shipment hazardous waste manifests (EPA Form 8700–22) for these potentially excluded wastes.

The database extractions, computations and findings of the impact analysis are presented in the Economic Assessment background document. The highlights of EPA's estimated economic impacts for this revision are as follows:

—236 applicable industrial hazardous waste streams, totaling 3.6 million tons in annual generation (before RCRA Subtitle C hazardous waste treatment) by an estimated 120 US facilities.

—As generated, these waste streams consist of 99% liquid (mainly organic liquids) and 1% non-liquid (sludge) waste forms.

—The 3.6 million annual tons of applicable waste (before RCRA Subtitle C hazardous waste treatment), represents 1.4% of the total RCRA hazardous waste universe (1993 BRS large generator total quantity = 258 million tons).

—Approximately 75% of the potentially excluded waste streams are identified by waste code F003 (spent non-halogenated solvents) plus a characteristic waste code (for example, D001), and 19% are identified by waste code F003 only.

—Applicable waste streams are located in 17 four-digit level SIC code industry sectors. 146 (62%) of the 236 applicable waste streams are generated by industries in SIC 28 (represented also by NAICS code 325).

—There are 51 different hazardous chemical constituents in the wastestreams *before treatment;* prevalent ones include: ethylbenzene, toluene, methyl ethyl ketone, methanol, ethyl acetate, xylenes, acetone, methylene chloride, and n-butyl alcohol.

—After RCRA Subtitle C treatment (mainly incineration), the 236 wastestreams result in the annual disposal of about 57,400 tons of treatment residuals, primarily in the form of incineration ash.

—Potential annual industry waste treatment residual disposal cost savings is estimated at $4.593 million, while annual reduction in truck shipment manifesting cost is estimated at $0.455 million. These two cost savings components represent a total annual cost savings estimate of $5.048 million. Applying –15% to +30% cost estimation uncertainty to this point-estimate (as explained in the background document), produces the associated cost savings estimation range of $4.29 to $6.56 million per year.

B. Regulatory Flexibility Act

Pursuant to the 1980 Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency publishes a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, a regulatory flexibility analysis is not required if the head of an agency certifies that the rule will not have a ''significant'' economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a ''significant'' economic impact on a substantial number of small entities. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et. seq.*

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that meets the Small Business Administration size standards established for industries as described in the North American Industry Classification System (see http://www.sba.gov/size/NAICS-cover-page.html).; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to

identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

The following discussion presents the facts for EPA's determination. EPA has examined this rule's potential effects on small entities as required by the RFA/SBREFA, and has determined that this action will not have a significant economic impact on a substantial number of small entities. As discussed in Section XII.A of this preamble, we have prepared an economic analysis of the potential effects of this rule, and have determined that the rule is expected to have a net beneficial effect on eligible entities, in the form of reduced environmental regulatory compliance costs for industrial waste management. The final rule allows small (and other size) entities voluntarily to exempt certain solid wastes (i.e. mixtures and derivatives of solid wastes listed as RCRA hazardous solely for the ignitability, corrosivity, and/or reactivity characteristics, which no longer exhibit any such characteristic, and which comply with RCRA land disposal restrictions), from compliance with the RCRA Subtitle C hazardous waste regulatory system. The economic analysis evaluates the extent to which both small quantity and large quantity industrial waste generators might be potentially eligible for cost savings under this rule, as a result of seeking this exemption. This proposed rule is voluntary, and the overall economic effect of this regulation for both small and large entities which are eligible to participate, is expected to be a net average annual reduction in industry regulatory burden and compliance costs. Consequently, because the net economic impacts and effects of this rule are beneficial rather than adverse, we have concluded that today's final rule will relieve regulatory burden for all small entities.

C. Paperwork Reduction Act (Information Collection Request)

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0801.12) and a copy may be obtained from Sandy Farmer by mail at OP Regulatory Information Division; U.S. Environmental Protection Agency (2137); 1200 Pennsylvania Avenue NW.; Washington, DC 20460, by E-mail at farmer.sandy@epamail.epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at http://www.epa.gov/icr.

Today's revisions of 40 CFR 261.3 do not include any new recordkeeping or reporting requirements. However, the revisions could reduce the burden estimate for existing RCRA information collection requirements, such as the Uniform Hazardous Waste Manifest (Form 8700–22A). As discussed in Section XII.A. of this preamble, today's rule could exclude approximately 54,700 tons of treated waste residuals (mainly incineration ash) per year. Assuming that these now-excluded wastes are shipped offsite for disposal, and assuming that an average truckload carries about 20 tons (of solids), today's rule could result in approximately 2,870 shipments per year that would no longer require Uniform Hazardous Waste Manifest. (This estimate is an upper bound, since many hazardous waste generators manage their waste on-site). The RCRA Hazardous Waste Manifest System ICR (No. 0801.12.) estimates an annual burden of 1.29 hours per shipment of hazardous waste. Therefore, today's rule could reduce the total burden associated with manifests by 3,702 hours per year. (The current burden associated with manifests is estimated to be 2,920,383 hours per year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, we generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes, with the final rule, an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, we must have developed a small government agency plan under section 203 of the UMRA. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's revision to the mixture and derived-from rules is voluntary, and because these revisions are less stringent than the current regulations, State governments are not required to adopt the regulatory changes. The UMRA generally excludes from the definition of ''Federal intergovernmental mandate'' duties that arise from participation in a voluntary federal program. The UMRA also excludes from the definition of ''Federal private sector mandate'' duties that arise from participation in a voluntary federal program. Therefore we have determined that today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132 (Federalism)

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. As explained in Section XI of this preamble, none of today's revisions are more stringent or broaden the scope of the existing Federal requirements. Therefore, States are not required to adopt the revisions to the mixture and derived-from rules in today's rules. Thus, Executive Order 13132 does not apply to this rule. Although section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with representatives of state governments in developing this rule, and included representatives of state governments as participants in the rulemaking workgroup. For an overview of EPA's consultations with the States, please see *Summary of Consultations with State Representatives for the Hazardous Waste Identification Rule (HWIR).*

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This final rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Because today's revision to the mixture and derived-from rules is less stringent than the existing program, it would not create any mandate on Indian tribal governments. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

''Protection of Children from Environmental Health Risks and Safety Risks'' (62 *FR* 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by us. This rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866 and because the environmental health or safety risks addressed by this action do not present a disproportionate risk to children.

H. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs us to use voluntary consensus standards in our regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards. Today's rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

I. Executive Order 12898: Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' as well as through EPA's April 1995, ''Environmental Justice Strategy, OSWER Environmental Justice Task Force Action Agenda Report,'' and National Environmental Justice Advisory Council, EPA has undertaken to incorporate environmental justice into its policies and programs. EPA is committed to addressing environmental justice concerns, and is assuming a leadership role in environmental justice initiatives to enhance environmental quality for all residents of the United States. The Agency's goals are to ensure that no segment of the population, regardless of race, color, national origin, or income, bears disproportionately high and adverse human health and environmental effects as a result of EPA's policies, programs, and activities. Today's rule is not expected to negatively impact any community, and therefore is not expected to cause any disproportionately high and adverse impacts to minority or low-income communities versus non-minority or affluent communities.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** A major rule cannot take effect until 60 days after it is published in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective August 14, 2001.

Technical Correction

XIII. What Technical Correction Is EPA Making in Today's Rulemaking?

In today's final rule, we also are correcting an error made in a previous notice. In the final rule published June 8, 2000, ''Organobromines Production Wastes; Petroleum Refining Wastes; Identification and Listing of Hazardous Waste; Land Disposal Restrictions; Final Rule and Correcting Amendments' (65

FR 36365), the entry for listed hazardous waste code U048 (o-Chlorophenol) in Table 1 of Appendix VII to 40 CFR part 268 (''Effective Dates of Surface Disposed Wastes (Non-Soil and Debris) Regulated in the LDRs-Comprehensive List'') was inadvertently removed. Today we are amending Table 1 of Appendix VII to 40 CFR part 268 to reinsert the entry for hazardous waste code U048. The LDR effective date for this waste code (all waste categories) was August 8, 1990.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Waste treatment and disposal.

40 CFR Part 268

Hazardous waste, Reporting and recordkeeping requirements.

Dated: April 30, 2001.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

2. Section 261.3 is amended by removing and reserving paragraph (a)(2)(iii) and revising paragraph (a)(2)(iv) and the first sentence of paragraph (c)(2)(i); and by adding paragraphs (g) and (h) to read as follows:

§ 261.3 Definition of hazardous waste.

(a) * * *

(2) * * *

(iii) [Reserved]

(iv) It is a mixture of solid waste and one or more hazardous wastes listed in subpart D of this part and has not been excluded from paragraph (a)(2) of this section under 40 CFR 260.20 and 260.22, paragraph (g) of this section, or paragraph (h) of this section; however, the following mixtures of solid wastes and hazardous wastes listed in subpart D of this part are not hazardous wastes (except by application of paragraph (a)(2)(i) or (ii) of this section) if the generator can demonstrate that the mixture consists of wastewater the discharge of which is subject to regulation under either section 402 or section 307(b) of the Clean Water Act (including wastewater at facilities which have eliminated the discharge of wastewater) and;

* * * * *

(c) * * *

(2) (i) Except as otherwise provided in paragraph (c)(2)(ii), (g) or (h) of this section, any solid waste generated from the treatment, storage, or disposal of a hazardous waste, including any sludge, spill residue, ash emission control dust, or leachate (but not including precipitation run-off) is a hazardous waste. * * *

* * * * *

(g)(1) A hazardous waste that is listed in subpart D of this part solely because it exhibits one or more characteristics of ignitability as defined under § 261.21, corrosivity as defined under § 261.22, or reactivity as defined under § 261.23 is not a hazardous waste, if the waste no longer exhibits any characteristic of hazardous waste identified in subpart C of this part.

(2) The exclusion described in paragraph (g)(1) of this section also pertains to:

(i) Any mixture of a solid waste and a hazardous waste listed in subpart D of this part solely because it exhibits the characteristics of ignitability, corrosivity, or reactivity as regulated under paragraph (a)(2)(iv) of this section; and

(ii) Any solid waste generated from treating, storing, or disposing of a hazardous waste listed in subpart D of this part solely because it exhibits the characteristics of ignitability, corrosivity, or reactivity as regulated under paragraph (c)(2)(i) of this section.

(3) Wastes excluded under this section are subject to part 268 of this chapter (as applicable), even if they no longer exhibit a characteristic at the point of land disposal.

(h)(1) Hazardous waste containing radioactive waste is no longer a hazardous waste when it meets the eligibility criteria and conditions of 40 CFR part 266, Subpart N (''eligible radioactive mixed waste'').

(2) The exemption described in paragraph (h)(1) of this section also pertains to:

(i) Any mixture of a solid waste and an eligible radioactive mixed waste; and

(ii) Any solid waste generated from treating, storing, or disposing of an eligible radioactive mixed waste.

(3) Waste exempted under this section must meet the eligibility criteria and specified conditions in 40 CFR 266.225 and 40 CFR 266.230 (for storage and treatment) and in 40 CFR 266.310 and 40 CFR 266.315 (for transportation and disposal). Waste that fails to satisfy these eligibility criteria and conditions is regulated as hazardous waste.

PART 268—LAND DISPOSAL RESTRICTIONS

3. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

Appendix VII to Part 268—[Amended]

4. Appendix VII to part 268 Table 1 is amended by adding the following wastestream in alphanumeric order (by the first column) to read as follows:

Waste code	Waste category	Effective date
* * * * * * *		
U048	All	Aug. 8, 1990.

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